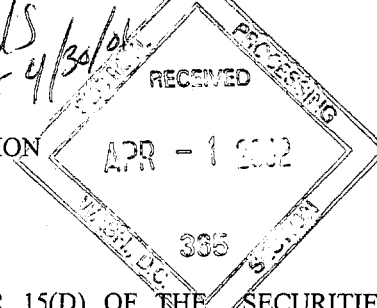




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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM ~~10-K~~ *AR/S*



(Mark One)



ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDING APRIL 30, 2001



TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM

TO

COMMISSION FILE NUMBER: 0-28010

MEDWAVE, INC.

(Exact name of Registrant as specified in its charter)

MINNESOTA

(State or other jurisdiction of
incorporation or organization)

41-1493458

(IRS Employer
Identification No.)

4382 ROUND LAKE ROAD WEST, ARDEN HILLS MINNESOTA 55112

(Address or principal executive offices, zip code)

Registrant's telephone number, including area code: (651) 639-1227

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to section 12(g) of the Act: COMMON STOCK, NO PAR VALUE

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X
NO _____

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

The aggregate market value of Common Stock held by non-affiliates of the Registrant, based on the last sale price of the Registrant's Common Stock in the over-the-counter market as reported by the Nasdaq Stock Market, Inc. on June 29, 2001, was approximately \$21,410,000. Shares held by officers, directors, and persons who own 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

As of June 29, 2001, 6,916,586 shares of Common Stock, no par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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Medwave®, Vasotrac®, Vasotrax™, Vasoport™ are trademarks of the Company.

Forward Looking Statements

This Annual Report on Form 10-K contains certain forward-looking statements. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as “may”, “will”, “expect”, “believe”, “anticipate”, “estimate”, “continued”, “likely” or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, including those set forth in Item 1.

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

Company Profile

Medwave was organized under Minnesota law in 1984. We are engaged exclusively in the development, manufacture, and sale of a non-invasive, continual blood pressure measurement and monitoring system and of related technology.

Our principal offices are located at 4382 Round Lake Road West, Arden Hills, Minnesota 55112 and our telephone number is 651/639-1227.

We have an April 30 fiscal year end.

Business

General

Medwave is a development stage company that currently employs seventeen (17) full-time employees. Since our inception, we have been engaged exclusively in the development of devices for monitoring and measuring blood pressure.

Blood pressure or, more precisely, arterial pressure, is the pressure that the blood exerts against the interior of the arterial walls. The level of the pressure depends upon the strength of the heart's contraction, the volume of blood in the circulatory system, the elasticity of the arteries, and the degree of capillary constriction impeding circulation. During the heart's relaxation phase, the diastole, blood pressure falls and rises when the heart muscle contracts. Clinically, blood pressure is commonly reported as three different values. Systolic and diastolic pressures are the maximum and minimum pressures during a single cardiac cycle, respectively. Mean pressure is the average pressure during the cardiac cycle.

Blood pressure and changes in blood pressure are critical indicators of the health and performance of the body's cardiovascular system. Blood pressure varies with age and by gender, such that young adults tend to have lower blood pressures than older adults and men tend to have higher blood pressures than women of the same age. Even in healthy bodies, blood pressure normally fluctuates during the day. For example, exercise, emotion, and exposure to the cold tend to cause blood pressure to rise, while it falls in instances of warmth, fainting, hemorrhage, and certain diseases. All hospital patients require measurement of their blood pressure and many surgical or critically ill patients require frequent or continual monitoring of their blood pressure. Continual monitoring of blood pressure is important for patients in operating rooms, surgical recovery rooms, intensive care units, and other critical care sites because of the acuteness of these patients' conditions and rapidity with which their conditions can deteriorate. Trend information obtained from successive blood pressure measurements plays an important role in the diagnosis, prognosis, and treatment of diseases.

Utilizing our proprietary technology, we developed the Vasotrac[®] APM205A system which monitors blood pressure, providing new readings approximately every fifteen heartbeats. We believe that the continual blood pressure readings and non-invasive qualities of the Vasotrac system make it the most advanced approach to blood pressure monitoring. In February 1995, we received clearance from the US Food and Drug Administration (FDA) to market the Vasotrac system. We have also developed a hand-held blood pressure monitor, the Vasotrax[™]. This hand-held monitor is based on the technology used in the Vasotrac system. In June 2000, we submitted a 510(k) notification to the FDA for review of the Vasotrax hand-held monitor. In August 2000, we received FDA clearance,

which has allowed us to begin marketing the Vasotrax in the United States for use on adult patients by trained medical personnel. In addition, and as a result of our supplier agreement with Nihon Kohden of Japan, we are developing a module of our Vasotrac continual non-invasive blood pressure monitor. The module is designed to be integrated into the other company's larger, more comprehensive systems.

Current Technology:

Invasive Arterial Catheter:

Currently, both invasive and non-invasive techniques are used to measure blood pressure. Invasive techniques employ the surgical placement of a catheter directly into an artery, an A-line. The fluid-filled catheter is connected to a pressure transducer and assorted tubing to produce beat-by-beat, continual blood pressure measurements. In addition, the catheter may be used to extract blood samples from which a number of diagnostic test results, such as blood gas information, may be obtained. Because our non-invasive Vasotrac system does not allow for the extraction of blood samples, invasive techniques offer a competitive advantage in this area. The surgical insertion of the catheter, however, takes about fifteen to twenty minutes, assuming no complications. Moreover, while such insertions frequently are performed without incident, serious complications can occur, including thrombosis (blood clot), air emboli (air bubble), and infection. Measurement errors may occur due to air bubbles, catheter clotting or movement, or changes in elevation between the pressure transducer and the level of the heart. Immediately following catheter withdrawal, firm pressure must also be applied over the arterial site for an extended period of time to avoid serious blood loss. Primarily because of its invasive nature, the A-line is generally used by clinicians in critical cases and for only relatively short time periods. The cost associated with inserting an arterial catheter can be significantly higher than non-invasive blood pressure monitoring.

As a general matter, we believe that non-invasive rather than invasive treatments and methods are preferred by clinicians for numerous medical conditions and processes, including the measurement and monitoring of blood pressure. Non-invasive techniques significantly reduce patient risk and increase patient comfort. In addition, the time and expense required to set up, maintain, and remove non-invasive equipment generally is substantially less than with invasive systems. We believe that, in many cases, patients in emergency departments and environments, critical care, operating rooms, cardiology departments, and pediatric environments could benefit from continual blood pressure monitoring after the point at which clinicians may now cease obtaining such readings due to concerns associated with prolonged or indefinite uses of invasive techniques.

Non-Invasive Blood Pressure Cuffs:

Many non-invasive blood pressure measurement techniques utilize a manually operated occlusive cuff around the upper arm. A relatively simple blood pressure instrument, called a sphygmomanometer, contains a cuff connected to a hand air pump and pressure gauge or mercury column. The cuff is inflated to a pressure above that of systolic pressure until the brachial artery is blocked, and then slowly deflated. During deflation, the clinician must listen to the pulse in the brachial artery. Upon hearing and properly interpreting the appropriate sounds, the clinician records the pressures shown on the gauge or mercury column. The cuff pressure occurring simultaneously with certain observed events within the circulatory or cuff systems are taken as the systolic and diastolic pressures. This process may take several minutes to complete, and in some patients will cause significant discomfort due to the squeezing of the cuff around the upper arm. Several clinical studies have been performed comparing the accuracy of this method with the invasive arterial catheter, and have shown a wide degree of variation with this method being caused by such things as environmental noise, improper cuff size, and readings taken too close in time.

Our Vasotrax hand-held monitor appears to have several advantages over a traditional sphygmomanometer. Recently many states have mandated that the reduction of mercury be accomplished by specified dates. Healthcare systems are searching for an alternative method to replace the thousands of mercury filled blood pressure sphygmomanometers currently in use. The Vasotrax can also produce a reading in approximately 15 seconds, whereas the sphygmomanometer may take several minutes to produce a reading. Another advantage is patient comfort because the Vasotrax does not require a blocking of the artery as does the sphygmomanometer. In addition, in the near future the Vasotrax will be capable of storing approximately 200 patient readings for up to 16 different patients.

An automated, non-invasive blood pressure monitoring system is already commonly used in critical care and operating room settings. The automated non-invasive blood pressure monitoring system currently dominating the market is the Dinamap[®] product, marketed by GE Medical Systems, a division of General Electric Company. The Dinamap[®] provides blood pressure measurements via automatic inflation and deflation of an occlusive cuff at predetermined intervals. It is reasonably reliable and simple to use. However, the Dinamap[®] product provides only intermittent measurements at one-to-ninety minute intervals, as selected by the clinician. Some patients suffer significant discomfort from the frequent cuff inflations. In addition, with cuff-based systems, arm circulation is cut off during each measurement, the arm holding the pressure cuff is unavailable for intravenous lines, and arm bruising and sleep interruption frequently occur. Also the manual and automatic cuff systems have not performed well in areas with a high degree of motion, such as in ambulances or cardiac stress labs.

In contrast to the sphygmomanometer and other cuff-based systems, our Vasotrac system and Vasotrax hand-held monitor require no inflatable cuff but instead contain a unique pressure sensor that is placed on the wrist. Beyond the comfort factor and greater versatility of our Vasotrac system and Vasotrax hand-held monitor, we believe that our Vasotrac has a very important advantage over cuff-based systems--more rapid readings that allow for more precise monitoring. Indeed the accuracy of the Vasotrac has been compared to an invasive arterial catheter with excellent correlation across a broad spectrum of patients. The Vasotrac produces an arterial waveform, not available on either manual or automatic cuffs, and provides significant improvement in patient comfort due to our measurement technique. The Vasotrac interfaces directly into existing patient monitoring systems by plugging an interface cable (the NIA V-Line) into the invasive pressure channel normally used for the arterial catheter. Moreover, this past spring we introduced a new software package that has the capability of monitoring a patient's blood pressure during excessive movement, such as is found in ambulances or a cardiac stress labs. The High Motion Tolerant (HMT) software was introduced at the NASPE (cardiology) meeting at the beginning of May 2001 with a high degree of interest expressed from attending cardiologists.

The contraindications for our Vasotrac system and Vasotrax hand-held monitor include patients on cardiopulmonary bypass, and patients with any condition in which rendering a pulsating pressure signal from the radial artery is not possible which may occur with severe arterial restrictions. Although there are contraindications for the system, we believe that, as a general matter, virtually no medical device is universally applicable for all patients at all times. As such, this should not be a critical factor for market acceptance. Moreover, given differences in individual bone construction, body weight, and physical condition, our products may not provide consistent readings or be usable on all patients. To date, however, we believe we have not detected any significant patient complications that are caused by the system.

For those critically ill patients who require continual blood pressure monitoring, invasive methods are currently the clinician's technology of choice. Given the attractiveness of non-invasive monitoring, however, several companies have introduced or are introducing products for non-invasive continual monitoring of arterial pressure based upon several technologies. These technologies include pulse-wave velocity, partially inflated finger cuffs, partially inflated arm cuffs, and tonometry. We believe that none has gained wide acceptance within the clinical community for continually monitoring arterial pressure. This belief is based on previous, unsuccessful efforts of other companies to introduce accurate, continuous, and non-invasive blood pressure monitors, the absence of such products at major medical and other product shows, the lack of published advertisements, papers or studies about such products in respected scientific, medical and other journals, and anecdotal discussions with physicians and other medical personnel by our management.

We have focused on building a dealer network so that we can seek nationwide and ultimately worldwide sales coverage without the commensurate increase in sales staff and cost that would occur if the same coverage were sought by building our own employee sales force. During the year, we also began hiring a core team of sales professionals to work with the dealer network. The success of our product sales will depend upon the ability of dealers and/or sales professionals to sell the products to the pre-hospital (EMT/EMS) environment, hospitals, the post-hospital environment such as physician offices, and other markets. At this time, our dealers have not demonstrated that they have achieved the sales success we wanted. However, within the past several months we have expanded the number and broadened the type of dealers we are working with.

Our success is dependent upon the successful development and marketing of the Vasotrac system, the Vasotrac module, and the Vasotrax hand-held monitor as well as related technology. However, there can be no assurance that

our products or related technology will be successfully marketed or sold in sufficient quantities and at margins necessary to achieve or maintain profitability.

In late December 1999, we entered into an exclusive distribution agreement with 3Ci of Atlanta, Georgia, a hospital based distributor sales company with nationwide coverage for critical care departments, for selling our Vasotrac system to the hospital market in the United States. This agreement was converted to a non-exclusive distribution agreement in December 2000 so that we could increase the number of our direct sales employees and expand our distribution network. In addition, in the fall of 2000, we entered into a non-exclusive agreement with 3Ci for the sale of the Vasotrac hand-held monitor to the hospital market in the United States. In March 2001, 3Ci was acquired by Allegiance Healthcare – Respiratory Care. While we have not yet had the opportunity to meet with representatives of 3Ci/Allegiance Healthcare subsequent to that transaction, the parties have continued to conduct business under the terms of the current contract. At this point, however, we are unable to determine what effect, if any, the Allegiance Healthcare acquisition of 3Ci will have on distribution and sales of our products or the ongoing relationship of the parties. Although market visibility for the Vasotrac system from this relationship is noticeably higher than before, we have yet to see the order flow that would indicate successful market entry.

Between February 2000 and January 2001 we entered into several international distribution agreements in Austria, Canada, China, Germany, Hong Kong, Italy, Japan, Norway, South Korea, Spain, Sweden, Switzerland, and Taiwan. In the Asian markets, we are currently working with the distributors to obtain the necessary government clearances to be able to sell our Vasotrac system and Vasotrac hand-held monitor in those countries. In August 2000, we received the CE mark allowing us to sell the Vasotrac system in European Union Countries. In January 2001, we received the necessary clearances to be able to sell into the Canadian market. Although we have a distribution agreement in place in South Korea, we are currently exploring additional distribution alternatives due to low initial market penetration, and local concerns in the South Korean Healthcare Market. We were notified in the spring of 2001, that we received South Korean government clearance to market the Vasotrac system in South Korea.

In June 2000, we signed an agreement for distribution of the Vasotrac system with Nihon Kohden of Tokyo, Japan. Nihon Kohden is a very well known medical device company in the Japanese market, with close to 50% market share in patient monitoring. We have worked with Nihon Kohden to prepare the necessary requirements to obtain Ministry of Health clearance, which is required prior to sales commencing in the Japanese market. As part of our agreement with Nihon Kohden, Nihon Kohden issued a purchase order to us valued at \$250,000, which will be completely fulfilled at the time of Ministry of Health clearance. A portion of this order was pre-paid in January 2001. This payment has been treated as deferred revenue on our financial statements for the quarter ended January 31, 2001.

In September 2000, we also signed an OEM module agreement with Nihon Kohden that calls for us to develop and produce a Vasotrac module that will be integrated into the Nihon Kohden patient monitoring product family. As a part of this agreement, Nihon Kohden placed an initial order for Vasotrac OEM modules, to be delivered over the initial 18 months, and paid the Company a down payment of \$125,000, that was received in October 2000. This payment has been treated as deferred revenue on our financial statements for the quarter ended October 31, 2000.

At the end of November 2000, we began shipments of our Vasotrac hand-held monitor. We intend, over the next several months, to introduce numerous accessory products for the Vasotrac, such as more options for battery charging, carrying cases, and data downloading software. We are presently in discussions with several companies regarding distribution possibilities with the Vasotrac, in a variety of market segments and geographic locations.

Prior to the introduction of the enhanced Vasotrac system in October of 1999, we used both a limited number of employees for sales and marketing and a limited dealer network to sell the initial Vasotrac system. We used the feedback from initial customers of the Vasotrac system to enhance the Vasotrac system to make the system more user friendly. During the enhancement project, we reduced our sales and marketing employees and focused on the engineering required for the enhancement effort. After we introduced the enhanced Vasotrac system in October of 1999, we focused on building a dealer network so that we could seek nationwide sales coverage without the commensurate increase in sales staff and cost that would occur if the same coverage were sought by building our own employee sales force. We are currently adding our own sales employees to work with the dealers in order to provide better product support. We currently anticipate a direct sales force of approximately 10 employees that will work with and support a distribution network focused on the pre-hospital, hospital, and post-hospital environments. We are also currently looking for a distribution partner for the Vasotrac hand-held monitor outside the hospital market. The success

of our product sales will depend upon the ability of dealers and/or sales representatives to sell the products to the hospitals, their affiliates, and other markets. At this time, dealers have not consistently demonstrated that they will be successful.

Feedback from the dealers and from clinicians indicates that our current, enhanced Vasotrac system is much easier to use than the previous configuration. However, there can be no assurance that we will be able to successfully implement or effectuate adequate dealer distribution arrangements in order to achieve successful market penetration. The initial response regarding the Vasotrac hand-held monitor from focus groups and limited showings has also been favorable. However, we may need to establish additional distribution arrangements, and complement those arrangements with a number of "in-house" experts. The Vasotrac hand-held product will be targeted at the pre-hospital (EMT and EMS) market, the hospital market, and the post-hospital markets (sub-acute, skilled nursing homes, homecare, and physician offices).

Our short-term and long-term investments are being used primarily to increase our sales and marketing efforts and increase awareness of Medwave and our technology in the markets, to continue clinical testing of the Vasotrac system, the Vasotrac hand-held monitor and related technologies, to continually validate our technology against traditionally used blood pressure monitoring devices and to create peer-to-peer consensus regarding Medwave's technology. We spent \$1,142,685, \$1,122,247, and \$1,230,072 on research and development expense for fiscal years ending 2001, 2000, and 1999, respectively. We anticipate incurring significant additional losses from further development, testing, regulatory compliance and sales and marketing expenses for the foreseeable future. Over the next twelve months, we expect to spend in excess of \$850,000 for research and development, including amounts expected to be spent on clinical trials. Specifically, the funds are expected to be used to develop alternative sensors (including sensors for use in pediatrics, and disposable sensors), to sustain engineering support for manufacturing start-up, to continue development of the hand-held monitor, and to develop the Vasotrac OEM module. We do not expect to spend any material amount on equipment in connection with these initiatives. Even assuming only limited sales, we believe that our current investments will allow us to meet our cash requirements for approximately twenty-two months from April 30, 2001. If the development process for our products does not proceed as expected due to significant product design changes, market acceptance difficulties, unexpected difficulties in attaining cost-effective manufacturability or higher than expected sales and marketing costs, we may require additional capital at an earlier date. We may seek such capital through bank borrowing, equipment financing, equity financing, and/or other methods. Our financing needs are subject to change depending on, among other things, market conditions and opportunities, equipment or other asset-based financing that may be available, and cash flow from operations. Any material favorable or unfavorable deviation from our anticipated expense could significantly affect the timing and amount of additional financing that may be required. However, additional financing may not be available when needed or, if available, may not be on terms that are favorable to us or our shareholders. In addition, any such financing could result in substantial dilution to our existing shareholders.

We have incurred an accumulated deficit of \$15,779,409 from our inception through April 30, 2001. We expect to incur additional losses from development, testing, regulatory compliance, sales, and other expenses at least until we emerge from the development stage.

We have financed our activities through an initial public offering (IPO) in November 1995, and a series of earlier private placements of equity securities, including shares of Preferred Stock that were converted into Common Stock just prior to our IPO in November 1995. On March 6, 1998, we completed a private placement that raised approximately \$2,990,000 in gross proceeds. On March 20, 2001 and June 13, 2001, we completed the first round and the second and final round, respectively, of a private placement that raised approximately \$6,000,000 in gross proceeds.

Products Description

We believe that the continual blood pressure readings and the efficacious and non-invasive qualities of our Vasotrac system and Vasotrac hand-held monitor make them a new, superior approach to blood pressure monitoring. The system is designed to assist clinicians in the therapeutic management of their patients by providing frequently updated blood pressure readings in an easily obtained and comfortable manner. This microprocessor-controlled system consists of (i) a liquid crystal display, LED displays, a Central Processing Unit and a key pad, all housed in an aluminum case, (ii) a patient cable, and (iii) a pressure sensor. We require that the sensors be changed at a

minimum of every six months. This is intended to assure adequate sensor performance, and, as a side benefit, it provides us with an ongoing revenue stream.

The Vasotrac system monitors blood pressure using, as a key component, the pressure sensor placed on the wrist over the radial artery, a main artery in the arm. Over seven hundred (700) of our Vasotrac system monitors have been used for clinical studies, laboratory experiments, by sales professionals and distribution partners, and by our customers. The monitor has no moving parts and is composed of standard, off-the-shelf components. Although these monitors have been subjected to electrical testing of various durations, the product life expectancy has yet to be determined. The sensor and motor assembly are the only moving parts of the Vasotrac system and, as such, they are receiving the most attention from us for life testing. We have configured testing equipment for use in conjunction with the Vasotrac system to exercise these components continuously in an unattended mode. Testing and evaluation of these components are still in process.

The Vasotrac system and Vasotrax hand-held monitor utilize proprietary technology of the Company, which applies pressure to the artery as the pressure waveforms are measured by the sensor. Then, our proprietary algorithms analyze the pressure waveforms to calculate the systolic, diastolic, and mean readings of blood pressure approximately every fifteen heartbeats. The Vasotrac system displays systolic, diastolic, and mean blood pressure in millimeters of mercury (mmHg) as well as heart rate in beats per minute. The Vasotrax hand-held monitor displays systolic and diastolic blood pressure as well as pulse rate. These values are displayed after the clinical user manually presses the Vasotrax on the subject's radial artery for approximately 15 seconds.

The Vasotrac system is designed to be used by trained medical personnel in hospitals and other critical care sites where continual blood pressure monitoring is desirable. Patient pressures can be monitored audibly and visually by entering limits into the Vasotrac system alarm menu. Those values above or below the limits will be automatically brought to the attention of the clinician through audible and visual alarms. Given differences in individual bone construction, body weight, and physical condition, the system may not be usable on all patients. However, with proper placement, the system has been usable on all patients participating in our clinical studies conducted to date, and we believe that the system will continue to be usable on virtually all patients with wrist sizes larger than 11 cm. We do not believe, however, that market acceptance of the system is likely to be jeopardized by lack of universal applicability of the system for the population, although there can be no assurance in this regard.

Recently we introduced the NIA V-Line interface product, which allows the clinician to plug the Vasotrac directly into the pressure channel of the clinician's existing monitoring system, allowing for a true "Plug and Play" and capture of data into the clinician's central system. To our knowledge, no other non-invasive blood pressure device has this capability today. In addition, we recently introduced the HMT (High Motion Tolerant) software package, which is designed to allow the clinician to take continual non-invasive blood pressure readings on patients in circumstances where motion is prevalent. In these clinical environments, obtaining a valid blood pressure value with manual cuffs is a significant challenge for the caregiver, as it requires using a stethoscope that may be difficult to hear through due to high motion and accompanying noise. Also, it has been reported to us that automatic cuff systems have not functioned well in situations involving high motion, even if they are designed for this application. As such, the initial interest from the market, especially cardiology departments, has been favorable to the Vasotrac with HMT.

Our development of the Vasotrax hand-held blood pressure monitor may result in a product that has sales potential in both the professional market (doctors, nurses, and medical technicians) and the consumer market. We have finished development of the first generation of the Vasotrax hand-held monitor, and have received a 510(k) clearance from the United States Food and Drug Administration for use on adult patients by trained medical personnel. The Vasotrax is designed to make accurate blood pressure and pulse rate measurements without using a cuff or a stethoscope. To use the device, the clinician presses the device against the wrist and slowly increases the force. In about fifteen seconds, the device will display the blood pressure and pulse rate. We have shown the Vasotrax hand-held monitor to clinicians at Company sponsored market focus groups, as well as at recent industry trade shows, where initial interest in this product has been encouraging. We are currently negotiating with potential distribution partners for the Vasotrax in the pre- and post-hospital markets. Currently we do not have suitable distribution channels for the potential markets for the Vasotrax hand-held monitor and there can be no assurance that we will be able to implement or effectuate suitable arrangements for such markets. We ultimately may be required to have focused sales professionals with responsibility only for the market segments that the Vasotrax hand-held monitor addresses,

specifically the pre- and post- hospital markets. The technology employed in the hand-held device may also be useful in developing products for other markets.

Clinical Studies

We have conducted clinical studies for three purposes: (i) to aid the product development process, (ii) to obtain data for submission to the regulatory agencies, and (iii) to help us prepare marketing and sales information to promote greater awareness of the Vasotrac system and Vasotrax hand-held monitor. We have used two standards of comparison, the automated cuff and the arterial line (A-line). The automated cuff clinicals did not allow synchronization of measurements between the cuff and our system because of the different number of heartbeats required to produce readings for each method. Further, the cuff does not meet the accuracy objectives that we set for the Vasotrac system and Vasotrax hand-held monitor. For these reasons, the cuff proved to be of limited utility in our studies.

In contrast to automated cuffs, A-lines are believed to provide more accurate blood pressure measurements. Further, the A-line studies allow for data synchronization. By inserting an arterial catheter in the radial artery on one wrist and by placing the Vasotrac system (or the Vasotrax hand-held monitor) sensor on the radial artery of the other wrist, data was simultaneously recorded on a beat-by-beat basis. Our clinical studies were conducted at teaching hospitals under institutional review board controls and protocols. Generally, such review boards represent their respective hospital and include physicians that can make appropriate judgments regarding the safety of the study. The boards periodically review protocols for medical devices and maintain meeting minutes, which are subject to audit by the FDA.

Our initial clinical studies were performed on approximately 30 subjects, some of whom were healthy and some of whom were undergoing surgery. Results from a series of these studies comparing the Vasotrac system's readings with the A-line's readings were used in our 510(k) submissions to the FDA. Subsequent to the 510(k) submissions, we have conducted clinical trials on approximately 350 additional individuals. During our clinical trials conducted to date, the variance between synchronized Vasotrac system readings obtained from one arm of the patient and the comparative A-line readings obtained from the other arm was calculated by computing the standard deviation of error from more than 30,000 paired readings from the patients. Based on these measurements (which excludes a certain number of paired readings because we believe that these readings have been affected by artifact, patient level differences, arm-to-arm differences, or experimental error) the magnitude of this variance was calculated as a standard deviation of approximately 7, 5, and 7 mmHg for systolic, mean and diastolic blood pressure measurements, respectively. As such, the Vasotrac system compares favorably with those found in previous generations of non-invasive blood pressure measurement devices, such as the Dinamap™ cuff-based system with which we claimed "substantial equivalence" in our 510(k) submission to the FDA. In addition, these standard deviation values are below the crucial 8 mmHg standard deviation limit of clinical acceptability as defined by the Association for the Advancement of Medical Instrumentation ("AAMI") as the national standard for electronic or automated sphygmomanometers.

In our 510(k) Vasotrac submission to the FDA, we included not only clinical data, but also outlined a plan to continue testing and integrating the results therefrom into the Vasotrac system. Based on the foregoing and, most importantly, the improvement in the overall results of the system's performance subsequent to its 510(k) submission, we do not believe that applicable FDA regulations require, and therefore at this point do not anticipate, any need to submit to the FDA the post-510(k) clinical studies.

Although we believe that our current product design for the Vasotrac system and our clinical studies conducted to date provide an adequate basis to continue marketing the system, it will take widespread use and testing to verify that the Vasotrac system is usable under most conditions. We expect to continue conducting or supervising on-going clinical studies of the system on individuals with different characteristics and under various conditions until such time as the Vasotrac system receives general market acceptance. We cannot currently estimate the number of individuals to be tested or the amount of time and expense that will be required to perform and analyze these additional clinical studies in order to achieve general market acceptance for the system.

In March 2001, we completed clinical testing of the Vasotrac system in pediatric applications. We used this clinical information to file a 501(k) to the FDA requesting clearance to allow for the use of the Vasotrac system on pediatric

patients. In June 2001, we received 501(k) clearance from the FDA for use of the Vasotrac system in pediatric applications.

We are currently expanding our studies of our systems to determine if the possibility exists to use the current sensor technology on different sites of the patient's body.

The object of our continued studies is to refine the design of the system and to test the system on a greater number of patients with different characteristics and under various conditions, such as a wide range of blood pressure readings, until such time, if ever, the Vasotrac system and Vasotrax hand-held monitor may receive general market acceptance. In addition, we believe that the studies will help us to prepare better marketing and sales information as well as to promote greater awareness and market acceptance of our products toward the goal of attaining commercial viability for them.

Below is a summary of the clinical studies completed to date on the Vasotrac continual non-invasive blood pressure system:

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| a. Volunteer Study – University of Minnesota | June 1994 |
| b. International Multi Center Study | December 1997 |
| Tokyo's Women's Medical College, University of California,
University of Vienna, University of Lille, St. Antoine Hospital
and University of Minnesota | |
| c. Induced Hypotension – University of Vienna | August 1998 |
| d. Morbidly Obese Patients – University of Minnesota | September 1998 |
| e. Patient Comfort - University of Vienna | December 1999 |
| f. Volunteer Study II - University of Minnesota | June 2000 |
| g. Pediatric vs. Cuff - University of Minnesota | August 2000 |
| h. Patient Comfort – Virginia Tech | September 2000 |
| i. Vasotrac vs. Arterial Catheter – University of Arkansas, Children's' Hospital | February 2001 |
| j. Vasotrac vs Arterial Catheter - Children Cardiology - Boston Children's Hospital | In Process |

We have also conducted clinical studies to develop and validate the Company's Vasotrax hand-held blood pressure measurement technology. These clinical studies included 60 healthy subjects. For each subject an arterial catheter was inserted in one arm and several operators performed repeated blood pressure measurements from the opposite arm using the hand-held monitor. For each one of the operator's blood pressure measurements, the corresponding arterial blood pressure measurements were determined and compared for accuracy. The raw waveform data from the arterial line as well as the raw data from the hand-held device were also recorded and stored into our clinical database for further processing. The data from the first 45 subjects was used for product development purposes. The data from the last set of 15 subjects was recorded with the final design of the hand-held monitor. The results of the comparison between the arterial line blood pressure readings and the hand-held device on these 15 subjects was then referenced as part of our filing with the FDA for the hand-held device's 510(k) submission, which was filed in June 2000. As was the case for the Vasotrac system, the standard deviation values for the Vasotrax hand-held monitor were below the 8 mmHg standard deviation limit for clinical acceptability as established by AAMI. In August 2000, we received FDA clearance to begin marketing the Vasotrax hand-held monitor in the United States for use on adult patients by trained medical personnel. Future studies will be explored to determine the usefulness and accuracy of the Vasotrax hand-held monitor for use in pediatric patients.

Introduction of the Vasotrac system and Vasotrax hand-held monitor to additional foreign markets and/or market segments may require us to conduct further clinical studies in order to achieve both regulatory and general market acceptance. These clinical studies and the results obtained therefrom may require us to undertake additional product development efforts in order to sell the Vasotrac system and Vasotrax hand-held monitor in these countries and/or market segments.

Marketing

Our success depends primarily on gaining physician and hospital acceptance of our products. One focus of our marketing strategy must necessarily involve overcoming resistance of the medical community to the introduction of new techniques or technology. We will build educational material (video tapes, clinical workbooks) specifically about

blood pressure monitoring and the benefits derived from Medwave's technology. We believe that testing of our products has yielded favorable results compared to other non-invasive blood pressure monitors. Now we will strive to create more of a presence and awareness about our technology and the benefits it brings to the healthcare provider. We intend to accomplish this by increasing our presence at industry trade shows, increasing the number of people representing our products, placing advertisements in industry trade journals, enhancing our web site, increasing our public relations activity, and conducting industry "Symposiums" regarding blood pressure monitoring and the benefits derived from Medwave's technology.

Employees

As of June 29, 2001, we had 17 full-time employees. Of this number, eight are in sales, two are in manufacturing, four are in research and development, and the balance is in management or administration.

We anticipate we will hire additional employees within the next 12-month period, primarily in sales and marketing positions. We preliminarily estimate that these employees will increase employee-related expenses in excess of \$500,000 during the next twelve months. However, such requirements are subject to change and are highly dependent on the market acceptance of our products, our distribution methods, and existing employment market conditions.

Pricing and Distribution

We constantly are evaluating the marketable price of the Vasotrac system and the Vasotrax hand-held monitor. Such pricing takes into consideration the marketing process for the Vasotrac system and the Vasotrax hand-held monitor and can be expected to remain dependent on a number of factors, including manufacturing costs, prices of competitive products, distribution methods, volume discounts, and market acceptance. We believe that the Vasotrac system is currently priced slightly higher than the high-end automatic cuffs sold by our competitors. We believe, however, that our higher price will be supportable due to the superior features associated with our product over such automatic cuff devices.

In comparison to the costs associated with A-line procedures, we believe that the Vasotrac system will, on a per-procedure basis, result in savings for healthcare providers. Insertion of an A-line is an invasive surgical procedure requiring a physician. No matter how routine any such procedure may become, all invasive procedures retain the inherent risk of complications and have attendant direct and indirect costs associated with them. We believe that the cost for non-invasively monitoring the blood pressure of a patient with the Vasotrac system will be less than with an invasive A-line. We believe that this will give it a competitive edge in an increasingly cost-conscious healthcare industry.

We believe that a market also exists for us to sell our Vasotrac OEM module to other equipment companies, such as patient monitoring companies. We recently secured our first agreement to sell our Vasotrac OEM module with Nihon Kohden of Japan, a market leader in the Japanese market with approximately 50% market share in patient monitoring. These types of agreements offer the potential for wide-spread market penetration without the tremendous investment in resources, that would be expected if we were to attempt entry on such a wide scale ourselves. In addition, we expect that the volume commitments from such agreements should be multi-year and offer yields that would take a direct sales organization years to accomplish.

For additional information concerning our product distribution efforts and arrangements, see "General" above.

Patents and Proprietary Technology

We have applied for U.S. patents covering various aspects of Medwave's blood pressure technology. As of June 2001, nineteen U.S. patents relating to Medwave's blood pressure technology have been granted, and five U.S. patent applications are pending. We also have pending patent applications relating to our blood pressure technology in the European Patent Office, Australia, Brazil, Canada, China, India, Japan, and Russia. Most of our patents and patent applications relate to both the Vasotrac system and to the Vasotrax hand-held blood pressure monitor.

There can be no assurance that any pending U.S. or any foreign patents will be granted or, if obtained, that they, or those already granted to us, will sufficiently protect our proprietary rights. Although patents have been granted to us, and even if the patents for which we apply are granted, they do not confer on us the right to manufacture and market products if such products infringe on patents held by others. While we have reviewed prior art in connection with our patent applications, we have not undertaken or conducted any comprehensive patent infringement searches or studies. If any such third parties hold any such conflicting rights, we may be required in the future to stop making, using or selling our products or to obtain licenses from or pay royalties to others, which could entail significant expense and have a material, adverse effect upon us. Further, in such event, there can be no assurance that we would be able to obtain or maintain any such licenses on acceptable terms, if at all. We have, throughout the development process for the Vasotrac and Vasotrax products, been associated with various companies, institutions and individuals. Although we have no knowledge that any such companies, institutions or individuals have claimed, or have any basis for claiming, interests in our proprietary rights, there can be no assurance that such claims will not be threatened, asserted or perfected. Such claims, even if we ultimately prevail on the merits, could have a material, adverse effect upon us.

In addition to patent protection, we rely, to the extent possible, on trade secrets, confidentiality agreements, unpatented proprietary know-how, and our continuing development of new products.

Government Regulation

We are subject to FDA and other government regulations, including regulations with respect to marketing approval, manufacturing practices, packaging, labeling and complaint reporting. Medical devices "substantially equivalent" to existing systems continuously marketed since May 1976 may be marketed pursuant to a Pre-Market Notification Submission (a "510(k) Submission") with the FDA. The FDA finding of "substantial equivalence" for the Vasotrac system and the Vasotrax hand-held monitor does not in any way denote official approval of the device. Further, any representation that creates an impression of official approval of a device because it complies with the pre-market notification regulations is misleading and constitutes misbranding. Certain devices, including those which are not "substantially equivalent" to predicate devices, are subject to Pre-market Approval Application ("PMA") requirements and more stringent FDA reviews. In contrast to the 510(k) process, the PMA process generally occurs over a more protracted time period and requires more extensive clinical data.

In January 1995, we filed a 510(k) Submission, including clinical data, with the FDA for the Vasotrac system. In February 1995, we received notice from the FDA that no further data would be required and that we could immediately commence marketing the Vasotrac system in the United States. In June 2001, we also received clearance from the FDA allowing use of the Vasotrac system on pediatric patients with a wrist size larger than 11 cm. In August 2000, we received notice from the FDA that we could immediately commence marketing the Vasotrax system in the United States for use on adult patients by trained medical personnel. Again, this does not constitute FDA "approval" of the Vasotrac system or Vasotrax hand-held monitor, but merely allows us to market the system in the United States. In addition, like all medical device manufacturers, we must implement, maintain and follow the FDA's Quality System Regulation ("QSR") and Good Manufacturing Practices ("GMP"). We believe our primary manufacturing costs will be driven by initial scale-up and ultimate production levels and will not be significantly impacted by such requirements. Should we intend to market the Vasotrac system or the Vasotrax hand-held monitor for new or different uses, or should we significantly modify the system in a way that could significantly affect its safety or effectiveness, we would be required to again file a new 510(k) Submission with the FDA. Moreover, it is anticipated that with new product concepts developed by us, if any, various government clearances will be required prior to being able to sell the products.

In our initial 510(k) Submission to the FDA, we included not only clinical data, but also outlined our plans to continue testing, and integrating the results therefrom into the Vasotrac system. We do not believe that FDA regulations require, and therefore at this point do not anticipate, submission to the FDA of our post-510(k) clinical studies. Although the FDA has stated that the manufacturer is best qualified to make an initial determination of whether a new 510(k) Submission is necessary, the FDA can overrule a manufacturer's decision not to submit a new 510(k) Submission and take appropriate regulatory action. If we determine we need not submit any such new 510(k) Submission, including with respect to our post-510(k) clinical studies, and the FDA consequently takes regulatory action, we could be materially and adversely affected.

In February 2000 we completed a sales agreement with E-Wha International of Seoul, South Korea. As part of this agreement, we worked with E-Wha to submit extensive documentation to the South Korean FDA for review prior to sales commencing. We believe this submission process was completed in October 2000, and we have been notified by E-Wha that government clearance has been obtained.

During the Spring of 2000, we began working on gaining the CE Mark, which is required by European Union countries prior to commencement of sales into those countries. We have now satisfied the requirements and can now display the "CE Mark" on designated units of our Vasotrac system. In addition, we are completing the process necessary for ISO 9001-EN46001-EC Directive 93/42/EEC Annex II.3 approval. We expect to receive ISO 9001 approval in the summer of 2001. This would allow us to display the "CE Mark" on all of our products. Failure to receive the ISO 9001 approval, or delay in receiving approval may result, however, in material and adverse effects to us, including loss of the ability to sell products in European countries. In addition to this approval, we are also working on non-English versions for the Vasotrac system, which may be required in certain international markets.

In June 2000 we entered into an agreement with Nihon Kohden of Tokyo, Japan. As part of this agreement, we worked with Nikon Kohden to submit extensive documentation to the Japanese Ministry of Health for clearance of the Vasotrac System in the Japanese market. We expect clearance during 2001.

Warranty and Service

Our products are available with limited 12-month parts and labor warranty commencing at the date of shipment. When warranty repairs are necessary, we generally perform them at our headquarters. We also provide on-call technical support. We also service equipment on a time and materials basis.

RISK FACTORS

Our business and an investment in our company are subject to a number of risks, including those described in the preceding sections as well as those highlighted below.

We must develop a market for our products

We presently depend on our Vasotrac, Vasotrax, and/or our OEM module product line, the market acceptance of which is in its early stages. Our future is dependent upon the success of these products and similar products that are based on the same core technology. The market for these products is in an early stage of development and may never fully develop as we expect. We have sponsored, and will continue to sponsor or conduct clinical trials. We cannot be certain that such clinical trials will be completed, that they will have a positive outcome or that a positive outcome in these trials will be sufficient to promote widespread acceptance of our products within the medical community.

Our success is dependent on market acceptance

Medwave's success depends on market acceptance of the Vasotrac system, the OEM modules thereof, and/or the Vasotrax hand-held monitor. Such acceptance depends primarily on gaining customer (end-user) and institutional (hospitals, outpatient centers, ambulance companies, nursing homes and physician offices) acceptance of these products. We believe that testing of the Vasotrac system and Vasotrax hand-held monitor has yielded favorable results compared to other non-invasive blood pressure monitors. However, improper placement of the pressure sensor or improper use of the system may cause the readings produced by the Vasotrac system and Vasotrax hand-held monitor to be questionable. As a result, another key component of our marketing strategy will be to focus on training and education of clinicians in the correct use of the Vasotrac system and Vasotrax hand-held monitor. Also, given differences in individual bone physiology, body weight and physical condition, the Vasotrac system, the OEM modules thereof, and the Vasotrax hand-held monitor may not provide adequate readings or be usable on all patients. For example, if a patient's peripheral blood flow to his or her arms has been affected, these products may not function as specified. Other contraindications for these products may result from patients on cardiopulmonary bypass and patients with any condition in which rendering a pulsating pressure signal from the radial artery is not possible. To date, we believe we have not detected significant patient complications caused by the system. However, as with any relatively new product, complications may occur as the Vasotrac system, the OEM modules thereof, and the Vasotrax hand-held

monitor are used on a greater number of patients with different characteristics and under various conditions. The presence of any significant complications would necessitate additional research and evaluation to determine the impact of such complications. As with any relatively new medical device, complications may manifest as the device is used on a greater number of patients with different characteristics and under various conditions. Finally, we must overcome the resistance of the medical community to the introduction of new techniques or technology. We believe that this resistance may be exacerbated due to the fact that the blood pressure cuff has been in use for more than 100 years, and virtually all medical professionals are trained using cuff technology. Therefore, there can be no assurance that the Vasotrac system, OEM modules thereof, or the Vasotrax hand-held monitor will gain market acceptance. If these products do not gain market acceptance, our future would be jeopardized.

We must maintain and develop strategic relationships with third parties to increase market penetration of our product lines.

We distribute our products to domestic hospitals and targeted international markets primarily through distributors. We also have a Vasotrac system OEM modules sales agreement in place with Nihon Kohden, a well known medical device company in the Japanese market, with close to 50% market share in patient monitoring. We intend to enter into similar agreements with other major patient monitoring companies and to establish technology partnerships with other medical product and technology companies. Widespread acceptance of technology is dependent on our establishing and maintaining these strategic relationships with third parties and on the successful distribution efforts of third parties.

Many aspects of our relationships with third parties, and the success with which third parties promote distribution of our products, are beyond our control. We may be unsuccessful in maintaining our existing strategic relationships and in identifying and entering into future development and distribution agreements with third parties.

Our international sales expose us to unique risks.

In fiscal 2001, international sales accounted for approximately 20% of our revenue.

We believe that international sales will represent a meaningful portion of our revenue in the future. We rely on distributors to assist us with our international operations. In addition, we are exposed to risks from international sales, which include unexpected changes in regulatory requirements, tariffs and other barriers and restrictions and reduced protection for intellectual property rights. Moreover, fluctuations in the rates of exchange may increase the price in local currencies of our products in foreign markets and may price us out of the foreign market.

We may not have adequate intellectual property protection.

Although we believe that we have effective patent protection, our patents and proprietary technology may not be able to prevent competition by others. In addition, in the future our products may be found to infringe upon the rights of others. Any claims resulting in intellectual property litigation, whether defensive or offensive, could drain our resources and, if decided against us, materially adversely affect our business.

We rely on a single technology platform.

We believe that significant and expanding markets exist for the Vasotrac system, the Vasotrax hand-held monitor, and for additional products incorporating our proprietary technology. Currently we utilize one technology platform in both the Vasotrac system and the Vasotrax hand-held monitor. The technology platform is our sensor technology and the software algorithm. In addition, in September 2000 we entered into an agreement to incorporate the Vasotrac system technology into an OEM module. This OEM module is currently in the design phase. Reliance on a single technology platform creates substantial risks for us. If, for example, the Vasotrac system and the Vasotrax hand-held monitor are not successfully marketed, if they fail to meet customer needs, or if they are not accepted in the marketplace, we would be materially and adversely affected, our primary business focus would require re-evaluation and our ability to continue operations would be jeopardized. Additionally, there can be no assurance that other products utilizing our proprietary technology will ever be successfully developed or marketed. We have not undertaken any comprehensive patent infringement searches or studies. If the Vasotrac system or the Vasotrax hand-

held monitor were found to infringe on the patent rights of others or if third parties successfully asserted rights to the these products, we would be materially adversely affected.

We also intend to develop additional products based on our core technology. The technology employed in the Vasotrac system may be useful in developing products for other markets. We are early in considering the development possibilities of these new products so there can be no assurance that additional products will be successful either from a technical standpoint or from a manufacturing or customer acceptance standpoint.

We must continue to evaluate the design of our products

While our initial product development and clinical testing program for the Vasotrac system and Vasotrac hand-held monitor are complete, extensive use and evaluation of the design is necessary in order to assess whether the products, as currently configured, will broadly meet customer needs or be accepted as a viable alternative in the marketplace. We will continue to test the Vasotrac system and Vasotrac hand-held monitor to enhance their market acceptance. If the configuration of the system must be modified, there can be no assurance such modifications will be acceptable to customers or be technically feasible. Even if feasible, such modifications could result in significant delays and significant expenses. If such modifications require regulatory approval, additional significant delays could result. We could be materially and adversely affected by any of these developments.

In addition, we have recently entered in to an agreement to incorporate the Vasotrac system technology into an OEM module. Although sale of the Vasotrac system as an OEM module is intended to complement sales of the system as a stand alone product, it is possible that configuration as an OEM module will be the principal or customer preferred way of purchasing and using this product. The OEM module that is the subject of this first agreement is currently in the design phase. If the OEM module requires extensive additional research and design effort, such efforts could result in significant delays and significant expenses. It is also likely that OEM modules will require regulatory approval, which may result in additional delays. Any regulatory application must be submitted by any of the third party companies that use the OEM module. We could be materially and adversely affected by any of these developments.

Our products may require servicing; We may be subject to product liability claims

Our goal is to produce highly reliable Vasotrac systems, OEM modules thereof, and Vasotrac hand-held monitors that do not require excessive subsequent servicing. There can be no assurance, however, that we will be successful in achieving such goal. There also can be no assurance that additional problems will not occur, that additional servicing requirements will not be necessary or that any additional problems or servicing requirements, individually or in the aggregate, will not be significant, difficult to correct, time-consuming or prohibitively expensive. Further, the need for any such additional servicing may not be readily apparent to clinicians using the Vasotrac system, OEM modules thereof, or the Vasotrac hand-held monitor. We believe that actual or perceived excessive servicing requirements for the Vasotrac system, OEM modules thereof, or the Vasotrac hand-held monitor could materially and adversely affect market acceptance of the system or could raise product liability concerns. *See "Risk Factors -- We may be subject to product liability claims that exceed insurance coverage."* Although we plan to continue testing our products to determine the extent of their servicing requirements, there can be no assurance that we can precisely identify the exact scope of such servicing requirements.

We have limited manufacturing experience and capability

We currently have little manufacturing experience or capability, other than a limited ability to produce small quantities of the Vasotrac system and Vasotrac hand-held monitor. We have not developed, arranged for, or invested in any significant production tooling, nor have we contractually arranged for any significant third-party manufacturing capacity or agreements. There can be no assurance that we will be able to scale-up manufacturing of the Vasotrac system, OEM modules thereof, or the hand-held monitor for commercial production at quantities required to meet cost targets and profitability goals. If our manufacturing costs are higher than anticipated or if a lower-priced competitive product becomes available, we may not be able to produce and sell the Vasotrac system, OEM modules thereof, or the Vasotrac hand-held monitor competitively. In addition, there can be no assurance that subcontractors, on whom we will rely for functions we will not perform internally, will produce sufficient products at required quality and cost levels. We will be materially adversely affected if we are unable to scale-up manufacturing successfully or effectuate manufacturing arrangements on acceptable terms.

We currently have limited or single sources of supply

We currently purchase from outside vendors, on a purchase order basis, small quantities of virtually all components and subassemblies for the Vasotrac system and Vasotrax hand-held monitor. Should production rates increase, the supply of components and subassemblies will become more critical. At present, many components are supplied by one vendor or are made by hand without production tooling in our facility. Furthermore, we have no formal agreements with any of our vendors. Should a key vendor be unwilling or unable to supply any components or subassemblies required by us in a timely manner, we will be materially adversely affected.

We face substantial competition

We currently know of one other continual non-invasive blood pressure monitoring device on the market. However, that device uses a cuff to calibrate the blood pressure readings and we therefore do not consider the device to be directly competitive. We face substantial competition from numerous companies that manufacture and market noninvasive and invasive instruments for blood pressure measurement and monitoring. Several companies competing in the blood pressure monitoring market have significantly greater resources as well as established technologies and product reputations in the blood pressure monitoring field. Our ability to compete successfully in this market will depend on our ability to develop and market a technologically superior blood pressure monitoring or measurement system that provides cost-benefit, patient benefit, and improved staff effectiveness.

To compete successfully, we likely will need to develop and introduce new products that keep pace with technological advancements, respond to evolving consumer requirements and achieve market acceptance. We may be unable to develop new products that address our competition.

Our business plan contemplates an income stream from sales of replacement sensors that are compatible with only our monitors and OEM modules. We may be subject to price competition from other sensor manufacturers whose products are also compatible with our monitors. To mitigate this we developed proprietary sensor technology that provides and promotes the exclusive use of our proprietary sensors with our equipment. There can be no assurance, however, that such measures will preclude replacement sensor competition in the future.

The current widespread acceptance of non-invasive cuff technology and of the arterial line, and the lack of widespread acceptance of non-invasive technologies like ours, is an important competitive disadvantage that we must overcome in order to gain general market acceptance. In addition, the current technology involving cuffs and arterial lines has established cooperative relationships with large medical equipment companies and buying groups that we must also overcome in order to successfully compete. If we are not successful at overcoming such competition, our primary business focus would likely require re-evaluation with our ability to continue operations being jeopardized.

Our technology may become obsolete

The medical device industry is subject to rapid technological innovation and, consequently, the life cycles of products tend to be relatively short. We are engaged in a field characterized by extensive research efforts. There can be no assurance that new developments or discoveries in the field will not render the Vasotrac system or Vasotrax hand-held monitor obsolete. The greater resources of many of the companies currently engaged in research of blood pressure management may permit such companies to create, or respond more rapidly than Medwave to, technological innovations or advances.

Third-party payers may not approve payment for use of our products, and we may be affected by changes in health care laws

Our success in the United States may be related to the number of third party payers, such as Medicare, private insurance companies, health maintenance organizations, and other payers, that approve payment or reimbursement for the use of the Vasotrac system, OEM modules thereof, and the Vasotrac hand-held monitor and the amount of any such payments or reimbursements. If, for example, hospitals are not able to recover the cost of these products through reimbursement, they may be reluctant to purchase these products, with the result that our sales may be adversely affected. The health care industry and associated regulatory environment are dynamic and rapidly changing,

particularly with respect to proposals to reform Medicare and to control health care costs. This environment makes it impossible to predict the effects, including costs or impediments to development, that adoption of and changes in health care laws, rules and regulations may have on us and on our operations. Such developments could, however, materially and adversely affect our ability to market our products.

We depend on management and other key personnel.

Our success currently depends on the services of Tim O'Malley, our President and Chief Executive Officer, as well as our engineering group, which has sophisticated technical knowledge about the Vasotrac system. The loss of one or more of our key employees may hurt our business if we are unable to identify other individuals to provide us with similar services. We do not maintain "key person" insurance on any of our employees.

For us to emerge from the development stage, we will depend on our ability to hire additional employees, within the next 12 months, for key positions, primarily in sales and marketing positions. Competition for such employees is intense and there can be no assurance that we will be successful in hiring such employees on acceptable terms or when required, or in maintaining the services of our present employees.

We may not be able to manage growth.

If successful, we will experience a period of growth that could place a significant strain upon our managerial, financial and operational resources. Our infrastructure, procedures and controls may not be adequate to support our operations and to achieve the rapid execution necessary to successfully market our products. Our future operating results will also depend on our ability to expand our direct sales force and our internal sales, marketing and support staff. If we are unable to manage future expansion effectively, our business, results of operations and financial condition will suffer, our management will be less effective, and our revenues and product development efforts may decrease.

We may not continue to receive necessary FDA clearances or approvals.

Our products and activities are subject to extensive, ongoing regulation by the Food and Drug Administration and other governmental authorities. Delays in receipt of, or failure to obtain or maintain, regulatory clearances and approvals, or any failure to comply with regulatory requirements, could delay or prevent our ability to market our product line.

We may not receive approvals by foreign regulators that are necessary for international sales.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary from country to country. If we, or our international distributors, fail to obtain or maintain required pre-market approvals or fail to comply with foreign regulations, foreign regulatory authorities may require us to file revised governmental notifications, cease commercial sales of our products in the applicable countries or otherwise cure the problem. Such enforcement action by regulatory authorities may be costly.

In order to sell our products within the European community, we must comply with the European community's medical device directive. Future regulatory changes may limit our ability to continue to use the CE mark, and any new products we develop may not qualify for the CE mark. If we fail to obtain this authorization or fail to obtain authorization on future products, we will not be able to sell our products in the European community.

We may be subject to product liability claims that exceed insurance coverage.

We have obtained product liability insurance, including excess umbrella coverage, in the aggregate amount of \$10,000,000 covering the Vasotrac system and Vasotrac hand-held monitor. However, there can be no assurance that we will be able to maintain such insurance in amounts and with coverage that will adequately cover associated risks or that such insurance will be available in the future at premiums that can be economically justified. Lack of such insurance could expose us to substantial damages, which could have a material, adverse effect upon us.

We have a history of losses and may experience continued losses.

We have experienced losses every year since our incorporation. These losses have resulted because we have expended more money in the course of researching, developing and enhancing our technology and products and establishing our sales and marketing organization than we have generated in revenues. We expect that our operating expenses will increase substantially in the foreseeable future as we increase our sales and marketing activities, expand our operations and continue to develop our technology. It is possible that we will never achieve or sustain the revenue levels required for profitability.

We may need additional capital, which may be unavailable.

The commercialization of our product line and the development and commercialization of any additional products may require greater expenditures than expected in our current business plan. Our capital requirements will depend on numerous factors, including:

- our rate of sales growth--fast growth may actually increase our need for additional capital to hire additional staff, purchase additional component inventories, finance the increase in accounts receivable and supply additional support services;
- our progress in marketing-related clinical evaluations and product development programs, all of which will require additional capital;
- our receipt of, and the time required to obtain, regulatory clearances and approvals--the longer regulatory approval takes, the more working capital we will need to support our regulatory and development efforts in advance of sales;
- the level of resources that we devote to the development, manufacture and marketing of our products--any decision we make to improve, expand or simply change our process, products or technology will require increased funds;
- our facilities requirements--as we grow we may need additional manufacturing, warehousing and administration facilities and the costs of the facilities would be borne long before any increased revenue from growth would occur;
- market acceptance and demand for our products--although growth may increase our capital needs, the lack of growth and continued losses would also increase our need for capital; and
- financing strategies--our attempt to accelerate the otherwise lengthy purchasing processes of hospitals by offering programs as an alternative to outright purchasing and by providing purchasers with extended payment terms and financing options will require additional capital.

We may be unable to predict accurately the timing and amount of our capital requirements. We may be required to raise additional funds through public or private financing, bank loans, collaborative relationships or other arrangements earlier than expected. It is possible that banks, venture capitalists and other investors may perceive our capital structure, our history of losses or the need to achieve widespread acceptance of our technology as too great a risk to bear. As a result, additional funding may not be available on attractive terms, or at all. If we cannot obtain additional capital when needed, we may be forced to agree to unattractive financing terms, to change our method of operation or to curtail our operations.

Common stock which is available for immediate resale may depress our market price.

We have filed a registration statement with the Securities and Exchange Commission covering the potential resale by some of our shareholders of up to 2,765,793 shares of common stock. The existence of a substantial number of shares of common stock subject to immediate resale could depress the market price for our common stock and impair our ability to raise needed capital.

We may have to issue additional shares, without any additional payment to us, because of the look-back and anti-dilution rights granted to investors in our March 20th closing.

On March 20, 2001, we completed the first part of a private placement, selling to investors 136,025 units which provided gross proceeds of approximately \$870,000 to us (in each case, net of any investors who converted their March 20 investment into the units sold by us at the second closing held on June 13, 2001). The investors who purchased units at the March 20, 2001 closing but did not convert those into the units sold at the June 13, 2001 closing are referred to herein as the "March 20th investors." Each unit purchased by the March 20th investors consists of one share of our common stock (the "initial shares") and one warrant to purchase one and one-half shares of common stock. The per unit price of the units purchased by the March 20th investors was \$6.375. The per share exercise price for the warrants issued to the March 20th investors is \$6.425. According to the terms of the stock purchase agreement entered into by Medwave and the March 20th investors, if we issue any common stock within 180 days of March 20th (subject to certain exclusions, including any securities issued pursuant to our recently completed private placement) for less than the price per share paid by the March 20th investors, the March 20th investors have the right to receive more common shares, for no additional consideration, necessary to ensure that each investor's effective per share purchase price for his initial shares will equal such lower issuance price. Also, included with units purchased on March 20th is a look-back right entitling the investor to receive, for no additional consideration, a number of additional shares if Medwave's future gross revenue does not meet certain targets. The applicable gross revenue targets are \$1.7 million for the six months ending October 31, 2001, \$3.1 million for the nine months ending January 31, 2002, and \$5.0 million for the twelve months ending April 30, 2002. If we don't meet these gross revenue targets, the look-back provision gives each March 20th investor the one time right to receive such number of additional shares as would cause the investor's average purchase price per share for his total holdings of initial shares still held and additional shares to be reduced to the greater of \$2.00 or 80% of the average closing price of our common stock for the five days following the filing of our quarterly or annual reports reflecting revenue that does not meet the relevant revenue target. If we don't meet the gross revenue targets and the look-back rights are exercised by some or all of the March 20th investors, there will be dilution to other holders of Medwave stock. The maximum number of look-back shares that could be issued to March 20th investors is approximately 297,555 shares. If we are required to issue some or all of the 297,555 look-back shares to the March 20th investors, there would be dilution to all other holders of our common stock and, potentially, a negative effect on the market price of the Medwave's common stock.

A low stock price or failure to maintain a minimum of \$2.5 million of stockholders' equity could result in our being de-listed from the Nasdaq Market and subject us to regulations that could reduce our ability to raise funds.

If our stock price were to drop below \$1.00 per share and remain below \$1.00 per share for an extended period of time, or if we fail to maintain stockholders' equity of at least \$2.5 million (and do not meet alternative tests of either having \$35 million in market capitalization or \$500,000 in annual net income), or if we fail to maintain other Nasdaq continued listing criteria, Nasdaq may de-list our common stock from the Nasdaq Market. In such an event, our shares could only be traded on over-the-counter bulletin board systems. This method of trading could significantly impair our ability to raise new capital.

In the event that our common stock was de-listed from the Nasdaq Market due to low stock price, we may become subject to special rules, called penny stock rules, that impose additional sales practice requirements on broker-dealers who sell our common stock. The rules require, among other things, the delivery, prior to the transaction, of a disclosure schedule required by the Securities and Exchange Commission relating to the market for penny stocks. The broker-dealer also must disclose the commissions payable both to the broker-dealer and the registered representative and current quotations for the securities, and monthly statements must be sent disclosing recent price information.

In the event that our common stock becomes characterized as a penny stock, our market liquidity could be severely affected. The regulations relating to penny stocks could limit the ability of broker-dealers to sell our common stock and thus the ability of purchasers in this offering to sell their common stock favorably in the secondary market.

Our common stock is subject to price volatility.

The market price of our common stock has been and is likely to continue to be highly volatile. Our stock price could be subject to wide fluctuations in response to various factors beyond our control, including:

- quarterly variations in operating results;
- announcements of technological innovations, new products or pricing by our competitors;
- changes in, or failure to meet, financial estimates of securities analysts;
- the rate of adoption by physicians of Medwave's technology in targeted markets;
- the timing of patent and regulatory approvals;
- the timing and extent of technological advancements;
- results of clinical studies;
- the sales of our common stock by affiliates or other shareholders with large holdings; and
- general market conditions.

Our future operating results may fall below the expectations of securities industry analysts or investors. Any such shortfall could result in a significant decline in the market price of our common stock. In addition, the stock market has experienced significant price and volume fluctuations that have affected the market prices of the stock of many medical device companies and that often have been unrelated to the operating performance of such companies. These broad market fluctuations may directly and adversely influence the market price of our common stock.

Medwave shareholders are not entitled to cumulative voting

There is no cumulative voting for the election of Medwave directors. Accordingly, the owners of a majority of our outstanding stock may elect all the directors, if they choose to do so, and the owners of the remaining shares will not be able to elect any directors. Officers and directors of Medwave currently own approximately 9.2% of the outstanding shares of common stock.

Medwave's Board can create and issue different classes of stock without approval of shareholders

Under Minnesota law and our Articles of Incorporation, no action by Medwave shareholders is necessary, and only action of our Board of Directors is required, to authorize the issuance by Medwave of any of our undesignated stock, including designation of some such shares as preferred. Our Board of Directors is empowered to establish, and to designate the name of, each class or series of the undesignated shares and to set the terms of such shares (including terms with respect to redemption, sinking fund, dividend, liquidation, preemptive, conversion and voting rights and any preferences). Accordingly, our Board of Directors, without shareholder approval, may issue undesignated stock with terms that could adversely affect the voting power and other rights of holders of the common stock. The existence of undesignated stock may have the effect of discouraging an attempt, through acquisition of a substantial number of shares of common stock, to acquire control of Medwave with a view to effecting a merger, sale or exchange of assets or a similar transaction. The anti-takeover effects of the undesignated shares may deny shareholders the receipt of a premium on their common stock and may also have a depressive effect on the market price of the common stock.

Certain provisions of the Minnesota Business Corporation Act may have an anti-takeover effect

Medwave is subject to Section 302A.673 of the Minnesota Business Corporation Act. In general, Section 302A.673 prohibits certain publicly held Minnesota corporations from engaging in a "business combination" with an "interested shareholder" for a period of four years following the date of the transaction in which the person or entity became an interested shareholder, unless either the business combination or the share acquisition by which the shareholder became an interested shareholder was approved by a disinterested committee of the company's board of directors before the shareholder became an interested shareholder. For purposes of Section 302A.673, "business combination" is defined broadly to include mergers, assets sales, and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is any person or entity who, together with affiliates and associates, owns (or within the three immediately preceding years did own) 10% or more of the corporation's voting shares.

Medwave is also subject to Section 302A.671 of the Minnesota Business Corporation Act. Section 302A.671 provides that an "acquiring person" proposing to make a "control share acquisition" must disclose certain information to the target corporation and the target corporation's shareholders must thereafter approve the control share acquisition or certain of the shares acquired in the control share acquisition shall not have voting rights and shall be subject to redemption by the target corporation for a specified period of time at the market value of such shares. A "control share acquisition" is an acquisition of shares of an issuing public corporation which results in the acquiring person's voting power increasing from its pre-acquisition level to one of the following levels of voting power: (i) at least 20 percent but less than 33-1/3 percent; (ii) at least 33-1/3 percent but less than or equal to 50 percent; and (iii) over 50 percent. The definition of a "control share acquisition" specifically excludes acquisitions of shares from the corporation issuing such shares, and acquisitions pursuant to plans of merger or exchange that are approved by the shareholders of the corporation. Unless the disclosure provisions and the shareholder approval provisions of Section 302A.671 are met, the shares acquired in a control share acquisition that exceed the initial threshold of any of the new ranges of voting power described above do not have voting rights and are subject to the redemption by the target corporation.

We do not intend to pay dividends in the foreseeable future.

We have never declared or paid a cash dividend on our common stock. We currently intend to retain any earning for use in the operation and expansion of our business and therefore do not anticipate paying any cash dividends in the foreseeable future.

ITEM 2. PROPERTIES.

We lease property in Arden Hills, Minnesota. Our building lease expires in May 2002. The monthly lease payment is approximately \$3,050. We are generally responsible for taxes, insurance, maintenance, and other expenses related to the operation of the facility. Our production capacity is adequate for our present needs. We believe that the property has been adequately maintained and is suitable for our business as presently conducted.

ITEM 3. LEGAL PROCEEDINGS.

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Trading activity with respect to our common stock has been limited. A public trading market having the characteristics of depth, liquidity and orderliness depends upon the existence of market makers as well as the presence of willing buyers and sellers, which are circumstances over which we do not have control.

Our common stock began trading in November 1995 on the Nasdaq SmallCap Market under the symbol "MDWV". The following table sets forth the high and low closing sales price for the Common Stock during each specified period as reported by the Nasdaq Stock Market, Inc.:

<u>Fiscal 2000</u>	<u>High</u>	<u>Low</u>
First Quarter	\$9.00	\$ 7.50
Second Quarter	7.75	6.75
Third Quarter	7.188	6.375
Fourth Quarter	10.00	6.75

<u>Fiscal 2001</u>	<u>High</u>	<u>Low</u>
First Quarter	\$8.25	\$6.75
Second Quarter	7.625	7.063
Third Quarter	8.125	7.125
Fourth Quarter	7.50	4.00

There were approximately 175 record holders and 1,000 beneficial holders of our common stock as of June 29, 2001. On June 29, 2001, the closing price for our common stock was \$4.50. We have never paid a dividend on our common stock and do not intend to pay dividends in the foreseeable future.

In a private placement conducted from March to June, 2001, we issued units consisting of common stock and warrants to 67 accredited investors. In the first round of the private placement, on March 20, 2001 we issued 181,125 units, each unit consisting of one share of common stock and a five-year warrant to purchase one and one-half shares of common stock, for aggregate cash consideration of \$1,154,672. The warrants become exercisable six months after the date of issuance at an exercise price of \$6.425 per share. In the second round of the private placement, on June 13, 2001 we issued 1,212,865 units, each unit consisting of one share of common stock and a five-year warrant to purchase one share of common stock, in consideration of \$4,867,164 cash and the tender of 45,100 of the units acquired in the March 20, 2001 round. The warrants become exercisable six months after the date of issuance at an exercise price of \$4.25 per share. Miller Johnson Steichen Kinnard, Inc., which acted as our agent in the private placement, received a commission of \$602,184, a five-year warrant to purchase 13,603 shares at \$6.425 per share and a five-year warrant to purchase 121,287 shares at \$4.25 per share. We relied on Rule 506 under the Securities Act of 1933 for the offer and sale of these securities. Each investor represented in writing that the securities were being acquired for investment and, in addition, the certificates representing the securities bear a restrictive securities legend.

ITEM 6. SELECTED FINANCIAL DATA

Year Ended April 30

	2001	2000	1999	1998	1997
Revenue:					
Net Sales	\$555,233	\$486,132	\$509,530	\$593,012	\$72,942
Operating expenses:					
Cost of sales and product development	622,011	617,172	505,110	552,560	113,261
Research and development	1,142,685	1,122,247	1,230,072	1,033,145	816,099
Sales and marketing	1,157,149	823,373	855,153	1,091,780	555,888
General and administrative	602,564	691,771	506,621	491,229	529,831
Total operating expenses	3,524,409	3,254,563	3,096,956	3,168,714	2,015,079
Operating loss	(\$2,969,176)	(\$2,768,431)	(\$2,587,426)	(\$2,575,702)	(\$1,942,137)
Other income:					
Interest income (other expense)	116,532	215,488	367,529	238,965	331,670
Other Income	----	----	1,500,000	----	----
Net loss	\$ (2,852,644)	\$ (2,552,943)	\$ (719,897)	\$ (2,336,737)	\$ (1,610,467)
Net loss per share - basic and diluted	\$ (0.52)	\$ (0.47)	\$ (0.13)	\$ (0.48)	\$ (0.34)
Weighted average number of common and common equivalent shares outstanding - basic and diluted	5,522,363	5,475,886	5,398,331	4,916,654	4,789,242

Balance Sheet Data:	2001	2000	1999	1998	1997
Cash and cash equivalents	\$1,116,589	\$1,155,924	\$1,175,756	\$1,926,697	\$1,240,700
Working capital	1,461,596	3,007,302	3,965,613	2,903,011	3,888,440
Total assets	2,130,790	3,766,789	6,143,492	6,739,162	5,551,796
Total shareholders' equity	1,606,547	3,499,665	5,902,956	6,572,046	5,422,596

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Results of Operations

Year Ended April 30

	2001	2000	1999
Revenue:			
Net Sales	\$555,233	\$486,132	\$509,530
Operating expenses:			
Cost of sales and product development	622,011	617,172	505,110
Research and development	1,142,685	1,122,247	1,230,072
Sales and marketing	1,157,149	823,373	855,153
General and administrative	602,564	691,771	506,621
Total operating expenses	3,524,409	3,254,563	3,096,956
Operating loss	(\$2,969,176)	(\$2,768,431)	(\$2,587,426)
Other income:			
Interest income (other expense)	116,532	215,488	367,529
Other Income	----	----	1,500,000
Net loss	\$ (2,852,644)	\$ (2,552,943)	\$ (719,897)
Net loss per share - basic and diluted	\$ (0.52)	\$ (0.47)	\$ (0.13)
Weighted average number of common and common equivalent shares outstanding - basic and diluted	5,522,363	5,475,886	5,398,331

Fiscal year ended April 30, 2001 compared to fiscal years ended April 30, 2000 and April 30, 1999.

Operating revenue for fiscal 2001 was \$555,233, an increase of \$69,101 or 14.2% from fiscal year 2000 operating revenue of \$486,132. Operating revenue for fiscal 2000 was \$486,132, a decrease of \$23,398 or 4.6% from fiscal year 1999 operating revenue of \$509,530. The increase in operating revenue from fiscal year 2000 to fiscal year 2001 was primarily due to our adding direct sales representatives to support the dealer network. The decrease in operating revenue from fiscal year 1999 to fiscal 2000 was due to (i) dealers not devoting the sales effort that we had anticipated as we converted to a dealer network from a direct sales force and (ii) the focus on the engineering of the enhanced Vasotrac product and the Vasotrax hand-held monitor during the last two quarters of the 1999 fiscal year.

Operating expense for fiscal 2001 was \$3,524,909, an increase of \$270,346 or 8.3% from fiscal year 2000 operating expense of \$3,254,563. Operating expense for fiscal 2000 was \$3,254,563, an increase of \$157,607 or 5.1% from fiscal 1999 operating expense of \$3,096,956. The increase in operating expense from fiscal 2000 to fiscal 2001 relates primarily to increased sales and marketing expenses as we increased our direct sales representatives to support the dealer network and as we created marketing material to support the sales representatives and dealer network. However, part of this increase was offset by a decrease in general and administrative expenses as we did not have the cost of hiring a new CEO, an expense that was incurred in the fiscal year 2000. The increase in operating expense from fiscal year 1999 to fiscal year 2000 relates primarily to an increase in production costs and an increase in salary expense due to an increase in the number of sales employees and our new CEO as we increased sales efforts with the release of the enhanced Vasotrac system in October 1999.

The cost of sales and product development for fiscal 2001 were \$622,011, an increase of \$4,839 or 0.8% from fiscal year 2000 cost of sales and product development expense of \$617,172. Cost of sales and product development for fiscal 2000 were \$617,172, an increase of \$112,062 from fiscal year 1999 cost of sales and product development expense of \$505,110 or 22.2%. The increase in costs of sales and product development from fiscal 2000 to fiscal 2001 was the result of the start-up manufacturing costs associated with the Vasotrax hand-held monitor, which was introduced into the market in November 2000. The

increase in cost of sales and product development from fiscal 1999 to fiscal 2000 was the result of increased production costs as we discontinued the manufacturing of our original product and introduced our enhanced Vasotrac system in October 1999.

Research, development, and clinical expense for fiscal year 2001 were \$1,142,685, an increase of \$20,438 or 1.8% from fiscal year 2000 research and development expense of \$1,122,247. Research, development, and clinical expense for fiscal year 2000 were \$1,122,247, a decrease of \$107,825 or 8.8% from fiscal year 1999 research and development expense of \$1,230,072. The increase in research, development, and clinical expense from fiscal 2000 to fiscal 2001 was primarily related to the research and development of the Vasotrac hand-held monitor that was introduced in November 2000. The decrease in research, development, and clinical expense from fiscal 1999 to fiscal 2000 was related to the completion of the research and development of the enhanced Vasotrac system in October 1999.

General and administrative expense for fiscal year 2001 were \$602,564, a decrease of \$89,207 or 12.9% from fiscal year 2000 general and administrative expense of \$691,771. General and administrative expense for fiscal year 2000 were \$691,771, an increase of \$185,150 or 36.5% from fiscal year 1999 general and administrative expense of \$506,621. The decrease in general and administrative expenses from 2000 to 2001 was primarily due to the one-time expense incurred in fiscal 2000 relating to the hiring of a new President and CEO. The increase in general and administrative expenses from fiscal 1999 to fiscal 2000 was related to the hiring of a new President and CEO including cost of outside contractors used in the hiring process.

Sales and marketing expense for fiscal year 2001 were \$1,157,149, an increase of \$334,776 or 40.5% from fiscal year 2000 sales and marketing expense of \$823,373. Sales and marketing expense for fiscal year 2000 were \$823,373, a decrease of \$31,780 or 3.7% from fiscal year 1999 sales and marketing expense of \$855,153. The increase in sales and marketing expense from fiscal 2000 to fiscal 2001 relates primarily to increased sales and marketing expenses as we increased our direct sales representatives to support the dealer network and as we created marketing material to support the sales representatives and dealer network. The decrease in sales and marketing expense from fiscal year 1999 to fiscal year 2000 was due to the decrease in sales personnel as we focused on the engineering of the enhanced Vasotrac System released in October 1999. In addition, we experimented with several different sales distribution methods in fiscal 1998.

Other income of \$1,500,000 in fiscal year 1999 was derived from a technical evaluation agreement entered into in September 1998.

Interest income for fiscal year 2001 was \$116,532, a decrease of \$98,956 or 45.9% from fiscal year 2000 interest income of \$215,488. Interest income for fiscal year 2000 was \$215,488, a decrease of \$152,041 or 41.4% from fiscal year 1999 interest income of \$367,529. The decrease in interest income in fiscal 2001 from fiscal 2000 and fiscal 2000 from fiscal 1999 was a result of the use of investments to fund operations.

Liquidity and Capital Resources

The Company's cash, and cash equivalents, short and long-term investments were \$1,116,589 and \$3,240,765 at April 30, 2001 and April 30, 2000, respectively. We incurred cash expenditures of \$2,916,658 for operations for the fiscal year ended April 30, 2001.

With the cash and cash equivalents and with the \$4.4 million in net proceeds from the June 13, 2001 final round of our private placement of common stock and warrants, we believe that sufficient liquidity is available to satisfy our working capital needs for approximately twenty-two months from the end of fiscal year April 2001. We have no significant capital expenditure commitments and do not plan any significant sale of capital equipment.

Cash flows used in operations increased to \$2,916,658 in fiscal year 2001 from \$2,634,293 in fiscal year 2000, an increase of \$282,365 or 10.7%. In both periods cash flows were used primarily to fund operating losses, which were partially offset by non-cash expenses for depreciation and amortization. The primary use of cash in operations for

fiscal year 2001 was for increases in inventory, primarily due to our preparing for future anticipated sales as the result of our signing agreements with foreign distributors and our starting production on the Vasotrax hand-held blood pressure monitor, and for prepaid expenses primarily the result of deposit on a future inventory purchase and for prepaid insurance costs. Increases in accounts receivable, primarily due to sales late in the fiscal year and an increase in inventory as we increased production in anticipation of future sales, were the primary use of cash in operations for fiscal year 2000. These uses in cash were partially offset by increases in deferred income, primarily due to our contract with Nihon Kohden for OEM modules and a distribution agreement for the Japanese market, for fiscal year 2001, and increases in accounts payable, primarily from increased trade payables, for fiscal years 2001 and 2000.

Net investing activities used \$165,202 and \$74,940 of cash in fiscal years 2001 and 2000, respectively, for property and equipment additions, primarily for production tooling and molding for the Company's products, provided cash of \$2,093,439 and a net of \$2,547,151 for fiscal years 2001 and 2000, respectively, primarily due to the conversion of marketable securities into cash to be used for operations.

Financing activities provided \$949,086 and \$142,250 of cash in fiscal years 2001 and 2000, respectively. In fiscal year 2001, the proceeds were from the March 2000 first round of our private placement of common stock and warrants. In fiscal year 2000, the proceeds were from the exercise of stock options.

Impact of Inflation

Inflation has had no material effect on the Company's operations or financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS.

Not Applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Medwave, Inc.
(A Development Stage Company)

Financial Statements

Years Ended April 30, 2001 and 2000

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Report of Independent Auditors

The Board of Directors and Stockholders
Medwave, Inc.

We have audited the balance sheets of Medwave, Inc. (a development stage company) as of April 30, 2001 and 2000, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended April 30, 2001 and the period from June 27, 1984 (inception) to April 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Medwave, Inc. at April 30, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended April 30, 2001 and the period from June 27, 1984 (inception) to April 30, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
June 21, 2001

Medwave, Inc.
(A Development Stage Company)

Balance Sheets

	April 30	
	2001	2000
Assets		
Current assets:		
Cash and cash equivalents	\$1,116,589	\$1,155,924
Short-term investments	—	1,684,841
Accounts receivable, net of allowance for doubtful accounts of \$13,203 and \$-0- for 2001 and 2000, respectively	208,009	99,188
Inventories	467,632	257,877
Prepaid expenses	193,609	76,596
Total current assets	1,985,839	3,274,426
Investments	—	400,000
Property and equipment:		
Research and development equipment	218,292	216,464
Office equipment	113,086	109,898
Manufacturing and engineering equipment	285,504	126,652
Sales and marketing equipment	54,269	51,536
Leasehold improvements	31,613	31,613
	702,764	536,163
Accumulated depreciation	(557,813)	(453,805)
	144,951	82,358
Patents, net of accumulated amortization of \$126,012 in 2000	—	10,005
Total assets	\$2,130,790	\$3,766,789

	April 30	
	2001	2000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 278,887	\$ 216,067
Accrued payroll	45,666	51,057
Deferred revenue	199,690	—
Total current liabilities	<u>524,243</u>	<u>267,124</u>
Stockholders' equity:		
Common Stock, no par value:		
Authorized shares – 50,000,000		
Issued and outstanding shares – April 30, 2001--		
5,734,049 and April 30, 2000--5,499,596	17,385,956	16,436,870
Accumulated other comprehensive loss	—	(10,440)
Deficit accumulated during the development stage	(15,779,409)	(12,926,765)
Total stockholders' equity	<u>1,606,547</u>	<u>3,499,665</u>
 Total liabilities and stockholders' equity	 <u><u>\$ 2,130,790</u></u>	 <u><u>\$ 3,766,789</u></u>

See accompanying notes.

Medwave, Inc.
(A Development Stage Company)

Statements of Operations

	Year Ended April 30			Period from June 27, 1984 (Inception) to April 30, 2001
	2001	2000	1999	
Revenue:				
Net sales	\$ 555,233	\$ 486,132	\$ 509,530	\$ 2,216,849
Operating expenses:				
Cost of sales and product development	622,011	617,172	505,110	2,410,114
Research and development	1,142,685	1,122,247	1,230,072	9,115,881
General and administrative	602,564	691,771	506,621	4,506,675
Sales and marketing	1,157,149	823,373	855,153	4,575,732
Operating loss	(2,969,176)	(2,768,431)	(2,587,426)	(18,391,553)
Interest income	116,532	215,488	367,529	1,738,904
Other income	—	—	1,500,000	1,500,000
Net loss	<u><u>\$(2,852,644)</u></u>	<u><u>\$(2,552,943)</u></u>	<u><u>\$ (719,897)</u></u>	<u><u>\$(15,152,649)</u></u>
Net loss per share – basic and diluted	<u><u>\$(.52)</u></u>	<u><u>\$(.47)</u></u>	<u><u>\$(.13)</u></u>	<u><u>\$(5.15)</u></u>
Weighted average number of shares outstanding – basic and diluted	<u><u>5,522,363</u></u>	<u><u>5,475,886</u></u>	<u><u>5,398,331</u></u>	<u><u>2,943,740</u></u>

See accompanying notes.

Medwave, Inc.
(A Development Stage Company)

Statement of Changes in Stockholders' Equity

	Common Stock		Accumulated Other Comprehensive	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Loss		
Issuance of Common Stock at \$.15 per share in July 1984 for capital equipment donated	10,000	\$ 1,500	\$ —	\$ —	\$ 1,500
Assets donated to Company by officer in August 1984	—	1,145	—	—	1,145
Net income for the period of June 27, 1984 (inception) to April 30, 1985	—	—	—	235	235
Balance at April 30, 1985	10,000	2,645	—	235	2,880
Net income	—	—	—	1,393	1,393
Balance at April 30, 1986	10,000	2,645	—	1,628	4,273
Issuance of Common Stock in connection with stock split in July 1986	190,000	—	—	—	—
Net loss	—	—	—	(98,211)	(98,211)
Balance at April 30, 1987	200,000	2,645	—	(96,583)	(93,938)
Net loss	—	—	—	(131,931)	(131,931)
Balance at April 30, 1988	200,000	2,645	—	(228,514)	(225,869)
Net loss	—	—	—	(258,135)	(258,135)
Balance at April 30, 1989	200,000	2,645	—	(486,649)	(484,004)
Issuance of Common Stock at \$.975 per share in April 1990 for consulting services	3,500	3,413	—	—	3,413
Accrual of dividends payable on the Redeemable Convertible Preferred Stock, Series A	—	(1,145)	—	(21,343)	(22,488)
Net loss	—	—	—	(278,845)	(278,845)
Balance at April 30, 1990	203,500	4,913	—	(786,837)	(781,924)
Accrual of dividends payable on the Redeemable Convertible Preferred Stock Series A	—	—	—	(1,775)	(1,775)
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(9,711)	(9,711)
Net loss	—	—	—	(553,710)	(553,710)
Balance at April 30, 1991	203,500	4,913	—	(1,352,033)	(1,347,120)
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(10,649)	(10,649)
Accretion on the Redeemable Convertible Preferred Stock – Series II	—	—	—	(105,318)	(105,318)
Net loss	—	—	—	(1,371,031)	(1,371,031)
Balance at April 30, 1992 (carried forward)	203,500	4,913	—	(2,839,031)	(2,834,118)

Medwave, Inc.
(A Development Stage Company)

Statement of Changes in Stockholders' Equity (continued)

	Common Stock		Accumulated Other Comprehensive	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Loss		
Balance at April 30, 1992 (brought forward)	203,500	\$ 4,913	\$ —	\$ (2,839,031)	\$(2,834,118)
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(10,914)	(10,914)
Accretion on the Redeemable Convertible Preferred Stock – Series II	—	—	—	(118,197)	(118,197)
Net loss	—	—	—	(615,888)	(615,888)
Balance at April 30, 1993	203,500	4,913	—	(3,584,030)	(3,579,117)
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(11,185)	(11,185)
Accretion on the Redeemable Convertible Preferred Stock – Series II	—	—	—	(121,904)	(121,904)
Net loss	—	—	—	(646,480)	(646,480)
Balance at April 30, 1994	203,500	4,913	—	(4,363,599)	(4,358,686)
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(11,463)	(11,463)
Accretion on the Redeemable Convertible Preferred Stock – Series II	—	—	—	(125,732)	(125,732)
Net loss	—	—	—	(455,498)	(455,498)
Balance at April 30, 1995	203,500	4,913	—	(4,956,292)	(4,951,379)
Exercise of stock options and warrants	126,896	144,299	—	—	144,299
Initial public offering of Common Stock, net of expenses	1,610,000	6,833,491	—	—	6,833,491
Preferred Stock conversion	2,750,164	5,476,163	—	—	5,476,163
Accretion on the Redeemable Convertible Preferred Stock – Series I	—	—	—	(5,874)	(5,874)
Accretion on the Redeemable Convertible Preferred Stock – Series II	—	—	—	(64,838)	(64,838)
Accrual of dividends payable on the Redeemable Convertible Preferred Stock – Series X and Series I	—	—	—	(7,858)	(7,858)
Change in unrealized loss on investments	—	—	(33,245)	—	(33,245)
Net loss	—	—	—	(671,859)	(671,859)
Comprehensive loss					(705,104)
Balance at April 30, 1996	4,690,560	12,458,866	(33,245)	(5,706,721)	6,718,900
Exercise of stock options and warrants	128,178	305,837	—	—	305,837
Change in unrealized loss on investments	—	—	8,326	—	8,326
Net loss	—	—	—	(1,610,467)	(1,610,467)
Comprehensive loss					(1,602,141)
Balance at April 30, 1997 (carried forward)	4,818,738	12,764,703	(24,919)	(7,317,188)	5,422,596

Medwave, Inc.
(A Development Stage Company)

Statement of Changes in Stockholders' Equity (continued)

	Common Stock		Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at April 30, 1997 (brought forward)	4,818,738	\$12,764,703	\$(24,919)	\$ (7,317,188)	\$5,422,596
Exercise of stock options and warrants	119,658	484,058	-	-	484,058
Private Placement of Common Stock, in March 1998 at \$7.50 per share, net of expenses	440,000	2,992,209	-	-	2,992,209
Change in unrealized loss on investments	-	-	9,920	-	9,920
Net loss	-	-	-	(2,336,737)	(2,336,737)
Comprehensive loss					(2,326,817)
Balance at April 30, 1998	5,378,396	16,240,970	(14,999)	(9,653,925)	6,572,046
Exercise of stock options and warrants	58,200	53,650	-	-	53,650
Change in unrealized loss on investments	-	-	(2,843)	-	(2,843)
Net loss	-	-	-	(719,897)	(719,897)
Comprehensive loss					(722,740)
Balance at April 30, 1999	5,436,596	16,294,620	(17,842)	(10,373,822)	5,902,956
Exercise of stock options and warrants	63,000	142,250	-	-	142,250
Change in unrealized loss on investments	-	-	7,402	-	7,402
Net loss	-	-	-	(2,552,943)	(2,552,943)
Comprehensive loss					(2,545,541)
Balance at April 30, 2000	5,499,596	16,436,870	(10,440)	(12,926,765)	3,499,665
Exercise of stock options	53,328	-	-	-	-
Private Placement of Common Stock, in March 2001 at \$6.38, net of expenses	181,125	949,086	-	-	949,086
Change in unrealized loss on investments	-	-	10,440	-	10,440
Net loss	-	-	-	(2,852,644)	(2,852,644)
Comprehensive loss	-	-	-	-	(2,842,204)
Balance at April 30, 2001	5,734,049	\$17,385,956	\$ -	\$(15,779,409)	\$1,606,547

See accompanying notes.

Medwave, Inc.
(A Development Stage Company)

Statements of Cash Flows

	Year Ended April 30			Period from June 27, 1984 (Inception) to April 30, 2001
	2001	2000	1999	
Operating activities				
Net loss	\$(2,852,644)	\$(2,552,943)	\$ (719,897)	\$(15,152,649)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	104,451	62,988	64,115	788,173
Amortization	10,005	18,014	25,399	136,017
Loss on sale of equipment	-	-	-	7,375
Issuance of Common Stock for consulting services	-	-	-	3,413
Changes in operating assets and liabilities:				
Accounts receivable	(108,821)	(68,119)	28,549	(208,009)
Inventories	(209,755)	(119,939)	111,141	(467,632)
Prepaid expenses	(117,013)	(882)	(739)	(193,609)
Accounts payable	62,820	39,571	66,911	278,887
Accrued payroll	(5,391)	(12,983)	6,509	45,666
Deferred revenue	199,690	-	-	199,690
Net cash used in operating activities	(2,916,658)	(2,634,293)	(418,012)	(14,562,678)
Investing activities				
Purchase of property and equipment	(165,202)	(74,940)	(6,882)	(959,517)
Patent expenditures	-	-	-	(136,017)
Purchase of investments	-	(1,814,634)	(3,481,041)	(38,908,724)
Sales and maturities of investments	2,093,439	4,361,785	3,097,881	38,908,724
Proceeds from sale of equipment	-	-	3,463	21,663
Net cash provided by (used in) investing activities	1,928,237	2,472,211	(386,579)	(1,073,871)
Financing activities				
Net proceeds from issuance of Common Stock	949,086	142,250	53,650	11,904,880
Net proceeds from issuance of Convertible Preferred Stock	-	-	-	4,848,258
Net cash provided by financing activities	949,086	142,250	53,650	16,753,138
(Decrease) increase in cash and cash equivalents	(39,335)	(19,832)	(750,941)	1,116,589
Cash and cash equivalents at beginning of period	1,155,924	1,175,756	1,926,697	-
Cash and cash equivalents at end of period	\$ 1,116,589	\$ 1,155,924	\$ 1,175,756	\$ 1,116,589

See accompanying notes.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

1. Business Activity

Medwave, Inc. (the Company), a development stage company, is engaged exclusively in the development, manufacturing, and marketing of a proprietary, noninvasive system that continually monitors arterial blood pressure of adults, and in the development of related technology and products. Utilizing the Company's proprietary technology, the VASOTRAC® system monitors blood pressure continually, providing new readings approximately every 15 heartbeats. In 1997, the Company began development of a hand-held blood pressure measurement device. This hand-held device is based upon the technology used in the Vasotrac System.

2. Management's Plans Concerning Cash Flows and Ongoing Operations

The Company continues to experience net losses and has an accumulated deficit in stockholders' equity of \$15.8 million through April 30, 2001. The Company believes that net proceeds from its private placement completed in June 2001 (see Note 10) will be sufficient to fund its operations through April 30, 2002.

3. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less to be cash equivalents. Cash equivalents are carried at cost which approximates market value.

Investments

Short-term investments consist primarily of U.S. corporate securities and treasury notes with maturities of less than one year. Investments with a remaining maturity of more than one year are classified as long-term investments.

Investments are classified as available-for-sale and are carried at fair value, with unrealized gains and losses reported as a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included in investment income along with interest and dividends.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

3. Summary of Significant Accounting Policies (continued)

Inventories

Inventories are valued at the lower of cost or market on the first-in, first-out (FIFO) method. The majority of inventory consists of purchased components.

Property and Equipment

Property and equipment are stated at cost. Depreciation is provided using the straight-line method over estimated useful lives of the assets as follows:

Research and development equipment	3 – 5 years
Office equipment	3 – 7 years
Manufacturing and engineering equipment	18 months to 5 years
Sales and marketing equipment	18 months to 5 years

Leasehold improvements are amortized over the related lease term or estimated useful life of the assets, whichever is shorter.

Income Taxes

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between the financial reporting and the tax bases of assets and liabilities.

Revenue Recognition

The Company recognizes revenue at the time of shipment of the product, with appropriate provisions for estimated allowances.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

3. Summary of Significant Accounting Policies (continued)

Research and Development Costs

All research and development costs are charged to operations as incurred.

Product Warranty Cost

The Company's policy is to make provisions in the year of sale for the estimated future repair costs on products covered by warranty.

Net Loss Per Share

For all years presented, the Company's basic and diluted loss per share is the same because the effects of all options, warrants, and convertible securities were antidilutive.

Stock-Based Compensation

The Company follows Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for its stock options. Under APB 25, when the exercise price of stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

Impairment of Long-Lived Assets

The Company will record impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

4. Investments

The following is a summary of the investments available-for-sale as of April 30, 2000:

	Cost	Unrealized Losses	Fair Value
U.S. corporate debt securities	\$2,095,281	\$(10,440)	\$2,084,841

5. Capital Stock

In November 1995, the Company sold 1,610,000 shares of Common Stock in an initial public offering from which the Company received net proceeds of \$6,800,000.

In March 1998, the Company sold 440,000 shares of Common Stock in a private placement for \$7.50 per share from which the Company received net proceeds of \$2,992,209.

In March 2001, the Company sold 181,125 shares of Common Stock in the first round of a private placement for \$6.38 per share, resulting in net proceeds of \$949,086.

The March 2001 round of the private placement contains a "look-back" provision in which the participants can receive an additional 297,555 shares for no additional consideration in the event that certain conditions exist at specified dates through July 30, 2002.

6. Leases

The Company leases its office, research and development, sales, and production facility under an operating lease that expires May 31, 2002. Operating expenses, including maintenance, utilities, real estate taxes, and insurance, are paid by the Company. Total rent expense under operating leases was \$73,849, \$53,712, and \$52,566 for the years ended April 30, 2001, 2000, and 1999, respectively.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

6. Leases (continued)

Future minimum rental payments required under leases that have remaining terms in excess of one year as of April 30, 2001 are as follows:

Year ending April 30:	
2002	\$36,438
2003	3,036
	<u>\$39,474</u>

7. Income Taxes

At April 30, 2001, the Company had net operating loss carryforwards of approximately \$15,430,000 and research and development tax credit carryforwards of approximately \$540,000. These carryforwards are available to offset future taxable income through 2020; however, a portion of the net operating loss will begin to expire in 2002.

Included in the NOL is approximately \$527,000 of deductions resulting from disqualifying dispositions of stock options. These deductions currently have a full valuation allowance and when realized for financial statement purposes they will not result in a reduction in income tax expense. Rather, the benefit will be recorded as additional paid-in capital.

The Company's ability to utilize its net operating loss carryforwards to offset future taxable income is subject to certain limitations under Section 382 of the Internal Revenue Code due to changes in the equity ownership of the Company.

No income taxes were paid for the years ended April 30, 2001, 2000, and 1999, respectively.

Components of deferred tax assets are as follows:

	April 30	
	2001	2000
Net operating loss carryforwards	\$5,863,000	\$4,731,000
Research and development credit carryforwards	540,000	460,000
Less valuation allowance	(6,403,000)	(5,191,000)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

8. Stock Options and Warrants

The Company has a stock option plan that includes both incentive stock options and non-statutory stock options to be granted to certain eligible employees or consultants of the Company. The maximum number of shares of Common Stock currently reserved for issuance is 1,700,000 shares. A majority of the options granted have ten year terms and vest and become fully exercisable at the end of four years of continued employment.

Option activity is summarized as follows:

	Shares Available for Grant	Options Outstanding Plan	Non-Plan	Weighted Average Exercise Price Per Share
Balance at April 30, 1998	381,000	1,208,200	20,000	\$ 4.28
Granted	(126,000)	126,000	—	12.18
Exercised	—	(58,200)	—	.92
Canceled	17,000	(17,000)	—	9.59
Balance at April 30, 1999	272,000	1,259,000	20,000	5.14
Granted	(455,000)	455,000	—	6.98
Exercised	—	(63,000)	—	2.26
Canceled	291,000	(291,000)	—	12.38
Balance at April 30, 2000	108,000	1,360,000	20,000	4.34
Granted	(75,500)	75,500	—	7.13
Exercised	—	(79,000)	—	1.44
Canceled	157,500	(157,500)	—	7.56
Balance at April 30, 2001	190,000	1,199,000	20,000	\$ 4.28

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

8. Stock Options and Warrants (continued)

The following table summarizes information about the stock options outstanding at April 30, 2001:

Range of Exercise Price	Number Outstanding	Options Outstanding		Number Exercisable	Weighted Average Exercise Price
		Weighted Average Remaining Contractual Life	Weighted Average Exercise Price		
\$.75	130,000	3 years	\$.75	130,000	\$.75
1.25	255,960	2 years	1.25	255,960	1.25
2.00 - 2.25	264,040	4 years	2.23	264,040	2.23
3.00	30,000	4 years	3.00	30,000	3.00
5.25	55,000	5 years	5.25	55,000	5.25
6.75	285,000	9 years	6.75	78,750	6.75
7.13 - 7.50	72,000	9 years	7.28	7,500	7.50
8.00 - 9.25	42,000	7 years	8.78	11,000	8.80
10.00	35,000	7 years	10.00	35,000	10.00
13.50	50,000	7 years	13.50	30,000	13.50
\$.75 - \$13.50	<u>1,219,000</u>	5.3 years	\$ 4.28	<u>897,250</u>	\$ 3.15

Options outstanding expire at various dates during the period from 2002 through 2009. The number of options exercisable as of April 30, 2001, 2000, and 1999 was 897,250, 876,750, and 888,250, respectively, at weighted average exercise prices of \$3.15, \$2.55, and \$2.72 per share, respectively.

In connection with the IPO in 1995, the Company issued warrants to purchase 140,000 shares of Common Stock at an exercise price of \$6.00 per share. The warrants expire in July 2001.

In connection with the March 2001 round of the private placement, the Company issued warrants to purchase 289,799 shares of Common Stock at an exercise price of \$6.43 per share. The warrants expire in March 2006.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

8. Stock Options and Warrants (continued)

Pro Forma Disclosures

The Company has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, *Accounting for Stock-Based Compensation* (Statement 123), requires use of option valuation models that were not developed for use in valuing employee stock options.

Pro forma information regarding net loss and loss per share is required by Statement 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of Statement 123. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions for 2001, 2000, and 1999: risk-free interest rates ranging from 6.00% to 5.29%, respectively; dividend yield of 0%; volatility factor of the expected market price of the Company's common stock of .56, .57, and .68, respectively, and a weighted average expected life of the option of five years.

The weighted average fair value of options granted during the years ended April 30, 2001, 2000, and 1999 was \$3.49, \$3.40, and \$6.35 per share, respectively.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

8. Stock Options and Warrants (continued)

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

	2001	April 30 2000	1999
Actual net loss	\$(2,852,644)	\$(2,552,943)	\$ (719,897)
Pro forma net loss	(3,182,566)	(2,313,865)	(1,410,264)
Pro forma net loss per common share	(.58)	(.42)	(.26)

The pro forma effect on net loss for fiscal 2001, 2000, and 1999 is not representative of the pro forma effect on net loss in future years because it does not take into consideration pro forma compensation expense related to grants made prior to fiscal 1996.

9. Contracts

In September 1998, the Company entered into a technical evaluation agreement with an interested party related to its blood pressure technology, specifically its hand-held blood pressure device. The Company received and recognized other income of \$1,500,000 when the agreement terminated with no additional agreement with the interested party.

10. Segment Reporting

The Company's business activities are aggregated into one reportable segment, given the similarities of economic characteristics between the activities and the common nature of the Company's products and customers. The Company does not currently have any geographic area outside the United States that accounts for more than 10% of the Company's sales. The total sales outside the United States account for approximately 20% of the Company's sales.

Medwave, Inc.
(A Development Stage Company)

Notes to Financial Statements

April 30, 2001

11. Quarterly Financial Data

2001	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net sales	\$ 84,480	\$ 95,250	\$164,707	\$210,796
Operating loss	(719,269)	(783,179)	(764,143)	(702,585)
Net loss	(669,064)	(750,487)	(743,676)	(689,417)
Basic and diluted net loss per share	(.12)	(.14)	(.14)	(.12)
<hr/>				
2000				
Net sales	40,183	80,016	250,824	115,109
Operating loss	(646,735)	(656,762)	(694,958)	(769,976)
Net loss	(580,438)	(620,014)	(618,964)	(733,527)
Basic and diluted net loss per share	(.11)	(.11)	(.11)	(.13)

12. Subsequent Event

On June 13, 2001, the Company completed the sale of 1,212,865 shares of its Common Stock in the second and final round of the private placement at a price of \$4.25 per share, resulting in net proceeds of approximately \$4.4 million.

In connection with this round of the private placement, the Company issued warrants to purchase 1,334,151 shares of Common Stock at an exercise price of \$4.25 per share. The warrants expire in June 2006.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANT ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF REGISTRANT.

Directors and Executive Officers

The following table sets forth the names, ages and positions of the directors and executive officers of the Company as of June 30, 2001. A summary of the background and experience of each of these individuals is set forth after the table.

The directors and executive officer of the Company are:

Name	Age	Position
G. Kent Archibald	60	Chairman and Director
Mark T. Bakko	41	Chief Financial Officer and Secretary
William D. Corneliuson ¹	58	Director
Norman Dann ¹	74	Director
Keith A. Libbey ¹	64	Director
Timothy J. O'Malley	40	President, Chief Executive Officer, and Director

(1) Member of the Audit and Compensation Committees

All directors hold office until the next annual meeting of shareholders or until their successors have been duly elected and qualified. Executive officers of the Company are appointed by and serve at the discretion of the Board of Directors. There are no family relationships among the directors and executive officers. The Board of Directors has an Audit Committee, which (i) reviews the Company's annual financial statements, (ii) makes recommendations regarding the Company's independent auditors and scope of auditor services, (iii) reviews the adequacy of accounting and audit policies, compliance assurance procedures and internal controls, (iv) reviews non-audit service performed by auditors to maintain auditors' independence, and (v) reports to the Board on the adequacy of disclosures and adherence to accounting principles. The Board of Directors also has formed a Compensation Committee, which (i) reviews compensation philosophy and major compensation benefits for executives, (ii) administers the Company's Stock Option Plan, and (iii) approves executive officers' compensation.

G. KENT ARCHIBALD has been Chairman and a director of the Company since 1991. From 1991 to 1999 Mr. Archibald served as President, Chief Executive Officer, and Secretary of the Company. From 1988 to 1991, Mr. Archibald was a private consultant and investor. From 1978 to 1984, Mr. Archibald was founder, president and director of AVI, Inc., a medical device company acquired by 3M Company's Medical Products Division in 1984. Mr. Archibald holds a B.S. degree in electrical engineering and is a professional engineer in the State of Minnesota.

MARK T. BAKKO is the Chief Financial Officer of the Company. He has served in this position since February 1996. From 1984 to 1996, Mr. Bakko was with Deloitte & Touche LLP with his most recent position being a senior manager. Mr. Bakko has been a Certified Public Accountant since 1985 in the State of Minnesota. Mr. Bakko holds a Masters of Business Taxation and B.S.B.A. degree in Accounting from the University of Minnesota.

WILLIAM D. CORNELIUSON, has been a director of the Company since May 1999. Mr. Corneliuson is President of B.C. Holdings, Inc., a registered investment advisor. Mr. Corneliuson has been with B.C. Holdings, Inc. since 1993. Previously Mr. Corneliuson was President, Co-Founder, and Vice Chairman of the Board of Strong/Corneliuson Capital Management, Inc from 1976 to 1993.

NORMAN DANN, a director of the Company since August 1995, has extensive experience in the medical device industry. Since 1992, Mr. Dann has been a business consultant concentrating in the areas of venture capital, strategic planning, marketing and product development. Mr. Dann also currently serves as a director of Minntech Corporation, and several private companies. From 1980 to 1992, Mr. Dann served as an executive officer of and consultant to Pathfinder Ventures, Inc., a venture capital firm ("Pathfinder"), and served as a general partner of three of Pathfinder's funds and partnerships. From 1971 to 1977, Mr. Dann served as Vice President of Sales and Marketing and Senior Vice President of Development with Medtronic, Inc., a leading manufacturer of cardiac pacemakers and other medical products. In 1960, Mr. Dann founded The Dann Company, an independent representative and service organization for medical products, which was acquired by Medtronic, Inc. in 1971. Mr. Dann holds a B.S. degree in industrial engineering from Pennsylvania State University.

KEITH A. LIBBEY, has been a director of the Company since July 1999. Mr. Libbey is Chairman Emeritus of the Board of Directors of Fredrikson & Byron, P.A., a law firm in Minneapolis, Minnesota. Mr. Libbey has been with Fredrikson & Byron, P.A. since 1969.

TIMOTHY J. O'MALLEY is the President, Chief Executive Officer, and a director of the Company. He has served in these positions since October 1999. From 1984 until 1999, Mr. O'Malley was an employee of Siemens Medical Systems, Inc. Throughout his employment he served in a variety of technical, sales, marketing and general management roles. At the time of his departure from Siemens, Mr. O'Malley was Vice President/Division Manager of Siemens Medical Systems, Electromedical Division for North America. Prior to joining Siemens, Mr. O'Malley worked as a biomedical engineer at a small privately held company in the Chicago area, selling and supporting medical equipment service and maintenance agreements. Mr. O'Malley received his Associates of Applied Science degree in 1983 from Oakton College in DesPlaines, Illinois and attended DePaul University of Chicago from 1986 until 1991, with an emphasis in Business Management and Marketing.

COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Section 16(a) of the Exchange Act requires the Company's officers and directors, and persons who beneficially own more than 10% of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors, and greater than 10% shareholders are required by Exchange Act regulations to furnish the Company with copies of all Section 16(a) forms they file.

Based solely on its review of the copies of such forms received by it, or written representations from certain reporting persons that no Form 5 was required for such persons, the Company believes that during the fiscal year ending April 30, 2001, all filing requirements applicable to its officers, directors, and greater than 10% beneficial owners were complied with.

ITEM 11. EXECUTIVE COMPENSATION.

The following table sets forth certain information regarding compensation earned by or awarded to Timothy J. O'Malley, the President and Chief Executive Officer, during the Company's last three fiscal years ended April 30, 1999, 2000, and 2001. No other executive officer of the Company received total salary and bonus compensation in excess of \$100,000 for the fiscal year ended 2001.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Securities Underlying Options (# of shares) ¹	All Other Compensation
		Salary	Bonus		
Timothy J. O'Malley President and Chief Executive Officer	2001	\$180,000	----	----	----
	2000	96,808	----	225,000	----
	1999	----	----	----	----

(1) Number of shares of Common Stock subject to options that were granted during the year.

Option/SAR Grants In Last Fiscal Year

No options were granted during fiscal year 2001 to the executive officer named in the above Summary Compensation Table.

Aggregated Option/SAR Exercises In Last Fiscal Year And Fiscal Year-End Option/SAR Values

The following table sets forth certain information concerning each exercise of stock options during the year ended April 30, 2001 by the executive officer named in the above Summary Compensation Table and the aggregated fiscal year-end value of the unexercised options of such executive officer.

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Unexercised Securities Underlying Options at Fiscal Year-End (#)		Value of Unexercised In-the- Money Options at Fiscal Year- End (\$) ¹	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Timothy J. O'Malley	- 0 -	\$ - 0 -	56,250	168,750	---	----

(1) Based on the differences between the closing price of the Company's Common Stock at fiscal year-end and the option exercise price.

Compensation of Directors

Directors are not currently paid fees for attending meetings. Under the Company's Stock Option Plan, each non-employee director receives an option to purchase 30,000 shares of Common Stock upon his initial election to the Board. Pursuant to such provision, in January 2000 Mr. Archibald received a non-qualified option to purchase 30,000 shares of Common Stock at an exercise price of \$6.75 per share; in August 1995 Mr. Dann received a non-qualified option to purchase 30,000 shares of Common Stock at an exercise price of \$3.00 per share; in May 1999 Mr. Corneliussen received a non-qualified option to purchase 30,000 shares of Common Stock at an exercise price of \$8.94; and in July 1999 Mr. Libbey received a non-qualified option to purchase 30,000 shares of Common Stock at an exercise price of \$7.50. Each such option is for a term of ten years and vests over a four-year period. In addition, after three years of service each non-

employee director receives a ten-year non-qualified option for 10,000 shares, vesting after one year, each year he or she continues to serve as a director. Mr. Dann received an option for 10,000 shares in November 1998 at an exercise price of \$13.50, and an option for 10,000 shares in November 1999 at an exercise price of \$6.75, and an option for 10,000 shares in November 2000 at an exercise price of \$7.125.

The Company has non-compete and confidentiality agreements with its employees. In addition, the Company has a letter agreement of employment with Mr. O'Malley. The letter agreement outlines the terms of Mr. O'Malley's stock options and compensation plan. The letter agreement does not provide for any severance benefits. The Company does not have key man life insurance on Mr. O'Malley. The Company does not have an employment agreement with, or key man life insurance on, any other individual.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table sets forth the beneficial ownership of shares of Common Stock of the Company on June 30, 2001 by each of the executive officers named in the Summary Compensation Table set forth in Item 11 by each director, by all directors and current executive officers as a group and by all persons known by us to be beneficial owners of more than 5% of the Company's common stock. Except as otherwise indicated, each of the shareholders listed in the table or included within a group listed in the table possesses sole voting and investment power with respect to the shares indicated.

Name and Address	Shares Beneficially Owned ¹	Percent of Ownership
John R. Albers 3825 Gillon Avenue Dallas, TX 75205	443,619	6.4%
G. Kent Archibald 4382 Round Lake Road West Arden Hills, MN 55112	593,877 ²	8.2%
Aaron Boxer Revocable Trust Aaron Boxer, Trustee 5500 Wayzata Boulevard 8 th Floor - Suite 800 Minneapolis, MN 55416	504,539	7.3%
William D. Corneliuson 777 East Wisconsin Avenue Suite 3020 Milwaukee, WI 53202	402,600 ³	5.8%
Norman Dann 4382 Round Lake Road West Arden Hills, MN 55112	70,000 ⁴	1.0%
Keith A. Libbey 900 Second Avenue South 1100 International Center Minneapolis, MN 55402	21,700 ³	*
David B. Johnson 5500 Wayzata Boulevard 8 th Floor - Suite 800 Minneapolis, MN 55416	645,037 ⁵	9.2%
Tim O'Malley 4382 Round Lake Road West St. Paul, MN 55112	56,250 ⁶	*
All Current Executive Officers and Directors as a Group (6 persons)	1,204,427 ⁷	16.1%

* Less than 1%

- (1) Shares not outstanding but deemed beneficially owned by virtue of the right of a person or member of a group to acquire them within 60 days are treated as outstanding only when determining the amount and percentage owned by such person or group.
- (2) Includes options to purchase 367,500 shares of Common Stock which are currently exercisable or will become exercisable within 60 days of June 30, 2001, and 2,000 shares held by Mr. Archibald's son.

- (3) Includes options to purchase 15,000 shares of Common Stock which are currently exercisable or will become exercisable within 60 days of June 30, 2001.
- (4) Includes options to purchase 60,000 shares of Common Stock which are currently exercisable or will become exercisable within 60 days of June 30, 2001.
- (5) Includes 290,240 shares held by Mr. Johnson's spouse and minor children and 163,000 shares owned by a foundation, over all which he may be deemed to share voting and dispositive power, and warrants to purchase 70,000 shares of Common Stock which are currently exercisable or will become exercisable within 60 days of June 30, 2001.
- (6) Such shares are not outstanding but may be purchased upon exercise of options which are currently exercisable or will become exercisable within 60 days of June 30, 2001.
- (7) Includes options to purchase 568,750 shares of Common Stock which are currently exercisable or will become exercisable within 60 days of June 30, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

There are no related party transactions.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

- (a)(1) Financial Statements
See Part II, Item 8.

- (a)(2) Exhibits

See Exhibit Index on page following signatures.

- (a)(3) Financial Statement Schedules

None

- (b) Reports on Form 8-K

An 8-K Report was filed on March 22, 2000¹ concerning the March 20, 2001 round of the Company's private placement of common stock and warrants.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDWAVE, INC.

Date: July 27, 2001

By /s/ Tim O'Malley
Timothy J. O'Malley, President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Tim O'Malley</u> Timothy J. O'Malley	President, CEO, and Director (principal executive officer)	July 27, 2001
<u>/s/ Mark T. Bakko</u> Mark T. Bakko	Chief Financial Officer (principal financial and accounting officer)	July 27, 2001
<u>/s/ G. Kent Archibald</u> G. Kent Archibald	Director	July 27, 2001
<u>/s/ William D. Corneliuson</u> William D. Corneliuson	Director	July 27, 2001
<u>/s/ Norman Dann</u> Norman Dann	Director	July 27, 2001
<u>/s/ Keith A. Libbey</u> Keith A. Libbey	Director	July 27, 2001